IMPACT OF THE HIGH-COST OF LONG-TERM CONTRACEPTIVE PRODUCTS ON FEDERALLY SPONSORED FAMILY PLANNING CLINICS, WELFARE REFORM EFFORTS, AND WOMEN'S HEALTH INITIATIVES

:ING

 THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

WASHINGTON, DC, MARCH 18, 1994

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IMPACT OF THE HIGH-COST OF LONG-TERM CONTRACEPTIVE PRODUCTS ON FEDERALLY SPONSORED FAMILY PLANNING CLINICS, WELFARE REFORM EFFORTS, AND WOMEN'S HEALTH INITIATIVES

FRIDAY, MARCH 18, 1994

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2359–A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order.

For the last 4 years, the Subcommittee on Regulation, Business Opportunities, and Technology has pursued an inquiry into the pricing of drugs and medical devices developed through research partially or entirely subsidized by Federal taxpayers.

Our primary concerns have been, one, that small drug and device manufacturers have equal access to these federally subsidized technologies. Two, the consumers who are paying for this subsidized research realize a return on their investment, either in lower prices on federally subsidized medical breakthroughs or in licensed fee revenues to the Federal treasury.

During a February 10, 1993 hearing on the price of Norplant, a long-term contraceptive device commercialized in part through a $16 million taxpayer subsidy, the subcommittee reviewed a substantial differential between this product's Unites States and international price.

In some overseas markets, this American product sells for less than 10 percent of its U.S. price. Now, the manufacturers have posited a number of reasons for this differential. Today, the burdensome effects of that price and the price of another long-term contraceptive, Depo Provera, will be examined and described by our U.S. Surgeon General and health administrator.

The discussion seems especially timely today. The American people expect this Congress to enact welfare and health care reform. Both of these issues have bottom-line implications to the small businesses of our country.

In the context of this debate, there has been considerable discussion about denying women on welfare benefit increases when they have additional children. At present, liberals and conservatives are

fighting furiously over this politically and philosophically charged matter.

Meanwhile, real answers are getting lost in the rhetorical fog. For example, ensuring that women have access to safe, affordable contraceptives can in fact, promote individual responsibility and at the same time ensure that women have the means to succeed.

Welfare families get bigger in part because birth control is not available and often fails the mothers of our country. Setting up financial disincentives to having more children won't do the job. Women need health care services that allow them to gain new control over their lives.

Virtually every public health professional testifying before this subcommittee has said that many women need long-term contraceptives, contraceptives which do not require daily decisionmaking and self-medication, but as we shall see, most clinics serving low-income women simply cannot afford to stock these products. Client choices diminish. Women have pregnancies they don't want. The welfare rolls grow as more women drop out of school and the work force in order to take care of unplanned families.

Dollar for dollar, one of the most important investments this Government can make is to ensure that women can obtain contraception that meets their health care needs.

Currently, long-term contraceptives such as Norplant cost American women $700 or more while they cost women in other countries just $23. According to some estimates, the actual cost of manufacturing Norplant is about $16. The exorbitant price of this product prohibits its use by uninsured, underinsured, and other low-income women.

For example, we have heard that 80 percent of the women in central Pennsylvania who are served by family planning clinics do not earn much money but do not qualify for Medicaid which pays for Norplant. That situation is particularly ironic given the fact that the American taxpayer paid for a significant proportion of its development.

Women who do not participate in Medicaid are 12 times less likely to receive long-term contraceptives such as Norplant. Availability is out of reach for two reasons: The initial cost is too high; and second, the cost of removal may not be covered.

Removal is a problem for users, whether or not they qualify for Medicaid. In fact, they are stuck. Access to long-term contraceptives should involve an affordable package of services including the insertion and the removal. The decision to start is a budget breaker for most users. The freedom to stop is a financial ambush.

One of our witnesses, Lisa Kaeser from the Alan Guttmacher Institute, will speak to this problem. The analysts at Guttmacher conducted an extensive and valuable survey on family planning clinics on the financial balancing act that clinical administrators must maintain in their ability to provide the broadest possible choice to the client.

The chair believes that it is time for the Clinton administration to mitigate the high cost of these contraceptives, especially for directors of federally supported family planning clinics.

Today, we are fortunate to have with us the Surgeon General, Dr. Elders. We had described the impact on family planning clinics

across the country and on the administration's public health and welfare reform agendas. Dr. Elders will also discuss with the subcommittee possible actions that the Government could take to lower the cost of contraceptives.

It is the chair's view, we are especially appreciative for having Dr. Elders today, that there are essentially only three avenues of Government intervention open at this time.

First, the Government could become the bulk purchaser of long-term contraceptives for distribution in federally subsidized family planning programs. The steep discount could be achieved with the savings passed on to the clinics.

Second, the Government could fund an accelerated research and development effort aimed at creating more products and more competition within the long-term contraceptive marketplace. Again, with the expectation that the price would decline and availability increase.

Finally, the administration could use its bully pulpit, its political and moral suasion to push more immediate public sector pricing for manufacturers of Norplant. The suppliers told our subcommittee in November that a discount price could be set 2 years from now. But we have good reason to look for a lower price much sooner, and the Government should be pursuing that end.

In our November 10th hearing, in questioning Dr. Mark W. Deutch of Wyeth about the high price of Norplant, I was told, "If the product came to be seen simply as a product for public sector clients and lower income users, we knew it would not be well accepted anywhere," said the Wyeth executive.

Now, we know from Wyeth's expensive advertising campaign — and I show this to my colleagues, the gentleman from Texas, Mr. Combest, and my colleague from Maine — we have seen the expensive advertising campaign that is being conducted by Wyeth to try to appeal with this device to affluent women. But I must say in response to the Wyeth justification for high prices, that their theory is about as novel a thought to justify high pharmaceutical prices as I have heard. I would like to say, in my view, this elitist school of pharmaceutical pricing is morally repugnant.

Drug prices ought to be based on development costs plus a reasonable profit, rather than some artificial elitist standard that assures a market of upper-income consumers.

Our other witnesses today, and we appreciate their input and their involvement, include consumers who have described their experience with Norplant, and representatives of family planning clinics who will describe how high contraceptive prices handicap the day-to-day operations of these important programs.

Before we go to Dr. Elders and our witnesses, I want to recognize my friend from Texas. This subcommittee has always worked in a bipartisan way and I am very fortunate to have such a fine ranking subcommittee member. I want to recognize the gentleman from Texas.

Mr. COMBEST. Thank you, Mr. Chairman.

Mr. Chairman, this morning we will definitely back into the issue of drug pricing for long-term contraceptive products. At the subcommittee's previous hearing in November, we heard from a series of witnesses that surprisingly agreed on a variety of issues.

They agreed the Norplant system is considered a breakthrough product in contraceptive technology. Witnesses also agreed that although the 5-year cost of this product is similar to other alternatives on the market, the up-front cost has caused access difficulties for some poor women.

I believe that cooperative efforts between Wyeth labs and the Federal Government should be further encouraged in an effort to establish a financing mechanism or other alternatives to increase the availability of this product.

I am fearful that the high decibel rhetoric by some who would have the Federal Government mandate prices on to private business would have devastating consequences. Not only could it lead to intransigence by corporate leaders, but in the end it would not result in any increased availability of the product to those who need it.

I believe it is fundamentally inconsistent to berate the lack of research and development of these socially sensitive products in the private sector and then advocate strict Government price controls when they are developed. I have no faith in Government bureaucrats knowing what the right price is for a pharmaceutical product or any other product. Once we set the dangerous precedent of Government price controls, it will result in shortages and inefficiencies in the marketplace.

Last, I would like to comment on the deafening silence from health care leaders as it relates to personal responsibility and abstinence. It is clear the fundamental shift away from teaching core values and abstinence and instead focusing on contraception and abortion has completely failed our youth. In the last 30 years, illegitimate births have increased almost 400 percent. In 1990, almost 2 million abortions are performed.

While teens are being bombarded with prosex messages from Hollywood, musicians and their peers, Government health official have spent little money advocating abstinence.

It is certainly time for health care leaders to offer our children a different, healthier message.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague, and look forward to working very closely with him as we have in the past on these issues.

Let me recognize next the gentleman from Maine, who has been a strong advocate of family planning programs, ensuring that women have access to these important health care services. He is a valuable member of the subcommittee. We appreciate him being with us.

Mr. ANDREWS. Thank you very much, Mr. Chairman.

Let me just say that I greatly appreciate your leadership on this very important issue, and I also want to welcome Dr. Elders and tell her how pleased I am that she is here with us.

It seems to me, Mr. Chairman, from all the work that we have done in this general area of taxpayers subsidizing research, critical medical research, we have been the object of a double-barreled ripoff. On the one hand, the taxpayers dig deep into their pockets to invest in this research, to subsidize this research, to make sure this research is successful, and then we find ourselves getting ripped off

again as consumers when we find these products that are developed as a result of these taxpayers' subsidized research facilities and programs coming back to us in the form of inflated prices.

As we look around the world in some of the other countries where these products are sold, we find that their consumers, who had nothing to do with investing in the product development, are getting a significantly lower price for the very same product. It is a double-barreled ripoff, Mr. Chairman.

I feel as if the U.S. Government is being played for as a sucker, that the taxpayers and the consumers of this country are having to pay the price. Frankly I think we need to be less concerned with ideological battles over the free enterprise system and whether we encroach upon companies that are selling those products and ripping us off and more practically concerned with the taxpayers of this country and the consumers of this country, and make sure we get a return for our investment, and we get fairness at the marketplace.

Now, it seems to me, Mr. Chairman, that in this very volatile subject of abortion, of health care choices for women, of course, we have a very difficult time in finding any middle ground with respect to this very volatile subject. The Nation and this Congress certainly is deeply divided over this subject.

But it seems to me we have a chance of finding some middle ground when it comes to providing education, when it comes to providing resources, when it comes to providing women throughout this country with some real choices in their lives and the ability to take the responsibility that some politicians like to preach about day after day and year after year.

At the very least, it seems to me that if we are investing taxpayers' dollars to provide women with choices with respect to contraception, that we should take the added responsibility on our shoulders in making sure they have access to that at reasonable prices.

For making this hearing possible, Mr. Chairman, and for your hot pursuit of this very important subject, I want to thank you.

Chairman WYDEN. Let me thank my colleague as well, and I share many of his views. I also happen to share the views of Mr. Combest as well, and I know Dr. Elders does on this matter, on individual responsibility. The challenge is to meld together individual responsibility with making sure that women have access to these critical resources.

Dr. Elders, let us call you at this time. We are very pleased that you could come. It is the practice of our subcommittee to swear all the witnesses who appear. Do you have any objection to being sworn at a witness?

Dr. ELDERS. Not at all.

[Witnesses sworn.]

Chairman WYDEN. Dr. Elders, we welcome you. You and your staff have been incredibly helpful to this subcommittee on a wide variety of issues, including nutrition and health services for women. We appreciate very much your being with us. We will make your prepared remarks a part of the hearing record. Please proceed as you feel comfortable.

TESTIMONY OF HON. M. JOYCELYN ELDERS, M.D., U.S. SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE

Dr. ELDERS. Thank you.

Mr. Chairman, Mr. Combest, Mr. Andrews, members of the subcommittee, I am pleased to be with you today to talk about the impact of high pricing of long-acting contraceptives such as Norplant and Depo Provera on access for American women.

While long-acting contraceptives have the potential for significantly expanding the contraceptive options available to American women, high prices remain a major barrier to access for the working poor, the young, the underinsured.

Norplant and Depo Provera represent significant breakthroughs in the last 30 years in the contraceptive technology available in this country. But they are priced out of the reach of far too many women. If reproductive choice is to be a reality in our country, reproductive choice must include access to the latest, most effective means of contraception.

At the outset, I want to express my personal appreciation to the Upjohn Company for persevering in its efforts to have Depo Provera approved for contraceptive use.

I also want to express appreciation for Wyeth's efforts on several fronts, including introducing Norplant to this country; its efforts in training professionals in insertion and removal; its ongoing research activities focused on women's health; its plans to provide a public sector price at the end of the initial 5-year period; and its efforts to make the method more available to poor women through the Norplant Foundation, which I understand has provided 13,000 kits to low-income women thus far.

However, I also want to make it clear that the fundamental problem remains. The price of Norplant and of Depo Provera is too high in this country for a large portion of young women, working women, to realize contraceptive equality.

As you know, I am committed to reducing the rates of adolescent pregnancy and unintended pregnancy in this country by ensuring that all woman have access to the widest possible range of contraceptive choices. While in Arkansas I was a strong advocate for making Norplant available as an additional option for women.

I supported Norplant training. I also worked especially hard to ensure that poor women who wanted it and were eligible for Medicaid or covered family planning services received information about and access to Norplant during the 60-day postpartum period of Medicaid coverage.

You see, Medicaid coverage goes up to 185 percent for poor women for up to 60 days postpartum. But in my State, Mr. Chairman, Medicaid coverage drops back to 29 percent after that 60 days. This is a woman who is making less than $4,000 per year.

You have heard me repeat many times, every child in America should be a planned, wanted child. With 57 percent of all births in the country considered unplanned or unwanted, we need to ensure that the newest, most highly effective methods of contraception are not beyond the reach of a majority of our women.

As you already know, 80 percent of the poor in our country were started by teenage families. We spent in 1992 $34 billion for fami-

lies started by children or teenagers, just on AFDC, food stamps, and Medicaid. That, to me, is a real major problem.

Norplant offers a very effective method to help women who want to plan and space their pregnancies because of its great advantage in providing continuous and long-acting contraceptive effectiveness, not requiring daily maintenance, being fully reversible, and it does not disrupt the sexual encounter.

Depo Provera is an injectable contraceptive with an effectiveness period of 3 months per injection. Depo Provera was approved by the FDA as a cancer palliative in 1960. It was not approved for marketing as a contraceptive until 32 years later, in 1992, even though many physicians, including myself, used it for many of our patients.

Depo Provera relies on a single injection every 3 months, after which the concentration of the effective compound gradually dissipates. Dosage appears ample in some studies, such that reinjection is not required for 6 months. Because the drug remains in the body longer than 3 months, it has an extended effect on ovulation, and return to fertility may be delayed several months after discontinuing use of Depo Provera.

One unique benefit of Depo Provera is the degree of privacy it affords users, with no daily coitus-related contraceptive to use or carry, and no visible rods outlined as with Norplant. Depo Provera allows a woman to be protected from unwanted pregnancy with complete privacy.

When first made available in the United States in early 1991, Wyeth set a universal price of $350, subsequently raised to $365 for the Norplant kit. However, when insertion and overhead costs are added, the overall charge for a Norplant injection can exceed $700, pricing it well out of the reach of many women.

At the same time, Norplant is sold internationally to Governments and nonprofit agencies in less developed countries for as low as $18, with an average of $23.

Why the huge difference in pricing overseas? While the Norplant product marketed in developing countries includes only the six capsules, in the United States it is packaged in a kit with surgical equipment and counseling materials.

Wyeth also provided extensive training to physicians for patient counseling in insertion and removal of the rods. However, neither the additional materials in the kit nor the additional training seemed to justify the high cost of Norplant in the United States.

Depo is manufactured by Upjohn Co. and is priced for contraceptive purposes at about $30 per injection, or $120 per year, not including the provider's fee for each office visit.

Upjohn has long been providing Depo Provera for noncontraceptive use for $12 per dose. It is odd that when this drug is approved for contraceptive use, which greatly expands the market for this compound, the price moves up instead of down, as one might expect.

Public funding to assist low and moderate-income women in obtaining contraceptives come from several sources. Medicaid, if you are poor enough. The Title X family planning, which has been grossly underfunded, only allowing $179 million for the 15 million poor women in America, less than $15 for women. Other Federal

programs also provide some funds, as well as State family planning programs.

A recent survey by the Alan Guttmacher Institute indicates that Medicaid is the largest single source of public funding for Norplant insertions, paying almost 90 percent of all the public funded insertions in 1992.

Most of the these insertions occurred during the 60-day postpartum period. As a State health director, I pushed to get Norplant during this period of coverage. It is unfortunate that our clients had to have a baby before they were provided access to this new contraceptive method. Depo Provera and particularly Norplant are virtually inaccessible for women whose income exceed the Medicaid threshold and who do not qualify for AFDC.

These women are often not covered for the implant by private plans; they are the working poor, the many women who are uninsured or underinsured. These women to offer lack a clear voice of advocacy here in Washington because they are so involved with the day-to-day grind of simply surviving, trying to stay off welfare.

Depo Provera and Norplant are also unavailable to adolescents, a group for whom easy access to reproductive health care is always a problem. Although Title X clinics are required to offer all contraceptive methods, they are not required any specific quantity of a particular method if this action is considered budget materially unsound.

Norplant and Depo Provera are provided on a first-come, first-served basis until the supply is exhausted, which often happens very quickly, as demonstrated by long waiting lists. Even in a tiny State like Arkansas, we had more than 2,000 women on the waiting list for Norplant, stimulating our State legislatures for the first time in the history of the State to approve $2 million to try and buy Norplant.

The combination of limited programming funding and the high cost of Norplant and Depo Provera presents clinics with the dilemma that for every woman provided a Norplant implant or placed on Depo Provera, several others are denied less expensive contraceptive methods, in effect, limiting the overall options of all clients and certainly reducing the number of clients served by the program.

When denial or limitations result in a low-birth-weight unwanted child, we often pay for this inequity — $2 billion for taking care of low-birth-weight babies in our nursery. I have already mentioned the $34 billion that we paid in 1992 for AFDC, food stamps, and Medicaid, up from $16 million in 1986.

Although Federal legislation mandates the drug manufacturers offer federally funded health care providers a price discount of 15.7 percent off their available best price, this is not nearly enough. How can you earn $5,000 a year and afford to spend $700 on a one-time insertion of Norplant?

I am pleased that Wyeth has announced that they will reduce the public sector price for Norplant after the first 5 years of distribution. However, how many additional families will be started?

Most likely the new 2-year, two-capsule Norplant system, soon to be released by Wyeth and the Population Council, will make Norplant less necessary, although a release date and potential have

not been made public. I would urge Wyeth to provide special pricing for nonprofit or public sector providers when the product is released.

I would also urge Wyeth to strongly consider offering Norplant capsules at a bulk rate to the public sector at a reduced, affordable price, without all the fancy packaging and accompanying brochures.

In summary, Norplant and Depo Provera are significant additions to the array of contraceptives offered in this country. After many years without new innovative contraceptive products, it is exciting that these two highly effective methods of contraception have made their way into the marketplace.

As committed public health professionals, our goal is to provide access for every woman in America to the contraceptive method of her choice at a reasonable and affordable price.

Yet, we are at a frustrating impasse because the fundamental obstacle to making long-term, highly effective contraceptives universally acceptable still remains a problem for the young, the working poor, the underinsured, and the uninsured. Too many women in this country are being denied access.

Mr. Chairman, I appreciate your assistance in drawing attention to this issue and the efforts you and your subcommittee are making to ensure that this problem is addressed in the very near future so that all women can enjoy contraceptive equality.

I want to thank you for holding this conference and for having me here today. Thank you.

[Dr. Elders' statement may be found in the appendix.]

Chairman WYDEN. Dr. Elders, thank you very much. Your statement is excellent and one that embodies many of my views. We so appreciate your advocacy in the fight you are making for low-income women.

The gentleman from Texas.

Mr. COMBEST. Thank you, Mr. Chairman.

Dr. Elders, thank you for coming today and for your statement. I advocated as well that the companies work as closely with you and others in the Government to do something to try it achieve the goals you have.

You made some excellent suggestions, in addition to ways that possibly can be obtained relative to packaging, relative to some of the devices and instruments which are in fact, part of the kit. It seems that we are somewhat in a dilemma in this instance.

In your testimony you mentioned that comparatively for other contraceptive products over the same period of time, there is a comparable cost. Obviously the reason for the high cost up front is because it is such a great technology, as you have indicated. All of those positive things that would accompany the use of Norplant or other types of implant devices that are advantageous over other types of contraceptive measures.

My concern is that, number one, given that participation with a Government research or some other type of Government program in trying to develop much-needed pharmaceuticals for this country, that that would be what would position a company in the place of potentially being regulated as to their cost.

So I wonder if in fact, it might discourage companies from wanting to participate with the Federal Government in the development of a product which is much needed in the marketplace.

I am also concerned that a company, again, given the fact that it is a comparable price, for example, Norplant, with other types of contraceptive measures, are going to go to their own personal expense and research in order to try to develop new technologies and pharmaceuticals by which all of the American people do benefit.

What is the right price? How is that determined? Who determines what the price is?

Dr. ELDERS. Obviously, Mr. Combest, I don't know how to determine what is the right price for any drug. I am a doctor and I am really not into drug pricing. I very much support the research that the Government does to try and increase and improve and make better drugs available to our citizens. I also am very well aware and I want the private industry to keep up their good work in producing and making available products for our society.

I guess my problem with this, if they were charging the same price or similar prices in other countries as we are being charged here, I would not have any problem whatsoever.

But to feel that we in America really spend Federal funds to help develop the product, and then for other countries to be able to get it at a much lower price than is offered to our poor and underserved, is a problem for me.

I realize that the company has spent a lot of time in education and training, because I was a part of those programs, and I realize they set up the foundation to help some poor women. But we know that that is not nearly enough, with where we are.

I do not know how to set drug pricing. I certainly think companies need to be rewarded for taking the risk. There is a certain amount of risk for putting new products on to the market, for their research and development.

We have to continue to support that kind of enterprise, and for a right and fair price. I don't understand how Europe can get it so much lower than we get it, but if this is a right and fair price, consider how much we are paying because of the number of women that are having unplanned, unwanted children. I think even if the Government had to make it available in our Title X clinics, it would be a very good investment.

Mr. COMBEST. I think — and there are a lot of other areas as well — we look at a lot of the costs in Government programs by what I have sort of considered in the past Government is basically just throwing money after the problem and not really looking at solving it, whether it is lack of good education and all of those things that lead to what I call institutionalized poverty. Government programs, I think, many times reward the inefficient by putting them into a position that virtually makes it impossible for them to come out. So, there are a lot of other areas we need to look at as well.

But isn't there a substantial difference in the way that the product is marketed in some of the other countries that would be used in determining the price, in the fact that this has got to be put in by a doctor, if the price, let's say — I believe the quick figures you

quoted in your testimony, as low as $18, and with an average price of about $23.

Let's take the average price of about $23. I have no idea what Norplant costs. It was made reference in testimony in November that it was maybe $16. So, let's take $16. There would be $7 profit if everything in that was dealt with. That still doesn't solve the problem of how do we pay for the physician to inject the device as well as remove the device——

Dr. ELDERS. That is separate.

Mr. COMBEST. Exactly. Later on, that problem still somewhat exists. It is probably as difficult for an individual making $5,000 a year, as was indicated, it would be very difficult for them to come up with $700 for the initial price, it probably would be as difficult to come up with $200 to have the doctor implant it. So, we have still got that hurdle to cover, the problem of at what point it becomes no longer feasible for a company to be involved in that, to be involved in the marketing of that product.

Maybe $5 or $7 per unit would be adequate, if that is all that was involved, and no advertisement and no further research, and none of the other things that might be involved in the marketability of a product.

I encouraged the manufacturers of varieties of pharmaceuticals that were before our hearing to try to come up with an alternative means to help finance this, to look at means by which, while it may be over a 5-year period of time, basically the same cost, if it is 20 cents a day over a 5-year period of time or whatever it may be, it is much easier to come up with that amount of money, to look at alternative means of approaching this and arriving at a more equitable price to compare with an individual's ability to pay. I encourage discussions that I understand have been ongoing with you and various manufacturers.

So I think the goal is the same. It may be just a different route that we want to take to get there. The real concern that I have, it would be the precedent that would be established that would be, number one, if we in fact, move that far in that direction and there is no other alternative that could be arrived at that could in fact, lead us there, of the precedent which would be established by the Federal Government determining what that price is going to be, what is the fair price — I don't know that industry and Government would come up with the same conclusion of what is a fair price — that would keep a company interested in doing the research that has helped us afford today the technologies we have, that would not discourage them from wanting to participate with the Government in a program that would then make them susceptible to the price controls, and what implications that might lead to other areas where we do need to come up with various types of programs or products that help people, particularly poor, which we are dealing with here.

So I think the goal of trying to reach that is laudable, but I again think in the long run that we may do as much damage if the only option left to us is Government establishing and controlling what their price might be. I would encourage very much an effort to continue to look at cooperative agreements and efforts with the companies to try to come up with a solution.

I just have one other quick question, Mr. Chairman.

I don't know for certain, Dr. Elders, that you would know the answer to this or not, but relative to the fact of the administration's concern about contraceptive devices, it is my understanding that the President's budget proposes to spend $585 million for foreign family planning programs, and only $192 million for U.S. family planning programs. Do you know why that discrepancy would exist in there?

Dr. ELDERS. Mr. Combest, I really don't know enough — I think I mentioned to you how much we were spending on Americans. I really do not know what the arrangement with the international family planning is and what the dollar figures should be.

Certainly, as the health director, I have been very concerned about the lack of appropriate or enough funding for us to provide the kind of services that we need to provide for poor women, that we are all trying to really reduce unplanned, unwanted pregnancies, reduce welfare, reduce crime, the things that we say that we are about.

Mr. COMBEST. Thank you, Dr. Elders.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague.

The gentleman from Maine.

Mr. ANDREWS. Thank you, Mr. Chairman.

Dr. Elders, I think you speak for all of us when you say you support very much the development of new pharmaceuticals to improve the quality of our life, to extend our life, to make and keep us healthier as Americans. I don't think anyone in this subcommittee wants to do anything to turn that tide.

But it seems to me from your testimony and from what other information has been able to receive, that there is some ripping off going on here. For example, following on Congressman Combest's point, you testified that a Norplant implant, the cost of that for an American woman could exceed $700. But overseas, we are talking about an average price, you testified, of $23.

Now, you mentioned a few additional things that might happen with respect to that service in the United States, counseling materials, some additional surgical equipment. But you asked the question, Why the huge difference in pricing overseas?

You conclude that neither the additional materials that you get in the kit in the United States nor the additional training received in the United States justifies the high cost in the United States relative to overseas. When we are talking about $700 versus $23, it seems to me that we are getting ripped off.

Dr. Elders, could you give us your feeling as to why there is such an enormous price discrepancy between overseas and the United States?

Dr. ELDERS. I think maybe in my testimony I didn't get it quite right. The cost of the kit is $365, by the time you pay for the doctor putting it in, so the $23 really only includes the cost of the six capsules and a trocar, whereas we package it in a fancy kit in America with the surgical instruments and all. We feel that was why the price went from $350 to $365. So, we do add that.

Then the company has invested in training physicians and nurses and nurse practitioners throughout the country. They have

done that, but I think even with all of their training, even with the kit, even, let's say, looking at $365, which is what the cost of the kit is, that still is a great disparity between $365 and $23. Again, it is in a kit, and so it is not a bulk purchase, and maybe a bulk purchase, the same as foreign countries purchasing it, it might be something the Federal Government could look at with the company to make it available to our family planning clinics.

But I think we all know that that is a very wide discrepancy. We are all concerned. If whoever produces it can produce that kind of price for overseas, for the international market, that would suggest that our market appears to be overpriced.

Mr. ANDREWS. It appears, indeed, that you are being very generous, I think, Dr. Elders. Some people would boil this down to a single word, "greed."

Do you think that that word would apply here?

Dr. ELDERS. Well, I feel that Wyeth in the past has really been a good corporate citizen in terms of helping women and maybe they have taken some beatings and they need to catch up, but on something that is so critical and so important to our society, at such a critical time, I feel that we need to do everything we can to make this form of contraceptive available for all women.

Mr. ANDREWS. Dr. Elders, as we move forward toward that goal, and certainly the Clinton administration is committed obviously to that goal, and as we move forward in this Congress in the debate, the great historic debate over health care and whether or not we are going to provide every American citizen with access to health care, could you tell us, talk a bit about the implications of the issue that we are discussing this morning and the President's health care plan?

If, for example, the health care plan that the President has proposed is passed, would then all American women have access to this type of contraceptive?

Dr. ELDERS. It is my understanding that if the health care plan is passed, that all women would have access to family planning. I am very concerned that family planning, at least in some of the plans, that there would be a 20 percent cost, it is not truly just in the preventive part of the plan, there would be no co-pay, but in this, for family planning, it is my understanding that there would be a copay.

However, the copay for women at the very bottom end of the scale, I think it is only something like $2, so it is really not a huge copayment. I think that this would make a very important, very significant difference.

I think we would begin to have a reduction in children born to children, we would reduce teenage pregnancy, make it more in line with many of the other developed industrialized countries.

I think we would markedly reduce the number, we talk a lot about abortions, we would markedly reduce the number of abortions that are performed, we would begin to educate our people so they could make responsible decisions. So, I very much feel that providing women's health would markedly improve the amounts of funds that we are paying out for other things. I often call that, as Mr. Combest has said, we pay an awful lot of money out for poverty, ignorance, and enslavement.

Mr. ANDREWS. Well, Dr. Elders, I appreciate that very much, and I think that is a goal that certainly I share, and I think that the administration needs to be congratulated for its leadership. I am concerned that as we expand the availability of these very important services and pharmaceuticals, that we as a Government need to not only protect the taxpayers who have invested in this technology but also those consumers who are paying for this technology. This huge gulf, $365 versus $23, the difference between what we pay in this country and what is paid for overseas, I think has to be addressed very seriously, particularly as we expand the availability of these services to women across the wide spectrum.

Dr. Elders, I appreciate your leadership on this issue and for your testimony today.

Mr. Chairman, I thank you.

Chairman WYDEN. Well, I thank my colleague.

In fact, both of my colleagues have asked a number of things that I am interested in.

Dr. Elders, again, our thanks to you for being here. As you know in this welfare reform debate, there are really two camps now in the Congress and I think in the country as well. One camp says that what you have got to do to solve welfare is to promote individual responsibility and you can do it by cutting resources.

The other camp says, no, individual responsibility isn't really the key thing, but what you have got to do is get some more money to the problem. It seems to me what you are saying, and something I very much agree with, is that there is a different approach that can bring the two camps together; that if you make these contraceptives affordable, we can promote individual responsibility among those on welfare, but making these drugs available at an affordable price will give people the means to be individually responsible.

Is that a fair characterization of what you are saying?

Dr. ELDERS. I think that is a very fair characterization of what I have been trying to say. It is something, I am very pleased — I have told people very often that in Arkansas, our teenage pregnancy rate has been dropping, has dropped 8.6 percent for each of the past 2 years. I realize that is not a miracle, but it has been going up in the rest of the country the past 2 years. I am really very proud of that. I think that one other thing that has helped is male responsibility, to address Mr. Combest's thoughts, is the fact that one thing that we did that I am still proud of, is that we put the father's social security card number on the birth certificate so that we had two responsible parents and not just one.

I think that helped because now we have young men realizing that we could deduct 17 percent of their salary until their child was 18, so that made them look at it. So, that has talked to me, that is addressing both the responsibility issue as well as the access issue, and I think we have to do both.

Chairman WYDEN. Well, that is my number one concern, because I have watched this debate get increasingly polarized. I think there is another approach — and I appreciate your nailing that down.

Let's go to some of the specifics now that I think illustrate the challenge for Government.

Isn't it correct to say that Upjohn and Wyeth have a monopoly on long-term contraceptive products?

Dr. ELDERS. At the present time, they are the two companies that have a long-term product that is on the market.

Chairman WYDEN. Now, on this issue of pricing, and I talked about various options in my prepared statement, you have touched on it. My colleague from Texas makes a very good point; nobody wants price controls, nobody wants some kind of Rube Goldberg Federal contraption where from the U.S. Congress you manage all the drug prices. But my understanding of bulk purchasing — I am interested in yours — is that basically what we want the Government to do is act like a smart shopper, we want the Government to use its purchasing power, invite companies to come on in, kind of like the VA does, and just act like any savvy shopper, to negotiate for the best possible price. Isn't that what we are talking about here with bulk purchasing?

Dr. ELDERS. I think that is what I am speaking of when we talk about bulk purchasing, because now we are moving away from individual kits. It will be available to the Government will purchase it and it will be available to all of the Title X clients, or all clinics all over the country.

I think that the Government has to negotiate again with the company. I think that certainly, we would certainly try at a State level and I have even talked with the companies since I have been here, and we have not made much headway. But I think I will say again, even if we can't get the price down or make them reduce the price, I still think it is worth the investment for the Government in order to reduce welfare and health care.

Chairman WYDEN. You noted that there are only two products in the market, and that of course doesn't seem like a whole lot of competition. That is one of the things that concerns me. In fact, I think in one of our earlier hearings in the last Congress, we had one expert say that women in the Third World had access to more contraceptive choices than do women in our country.

What about the idea of using the Government laboratories, particularly through HHS which has a branch that is looking at this to try to promote new contraceptive options, get more competition out there, so that when the Government acts like a smart shopper, it has got some more leverage?

Dr. ELDERS. I think you know that we all support more research and development. Our National Institutes of Health, certainly our Reproductive Branch has been working on this, and when they are ready, I think when they have been developed and they are ready for the market — of course, I think we still feel that our pharmaceutical companies have to take them and really do the final stages to really get them on to the market.

Chairman WYDEN. Tell us, if you would, about caprinol. We have heard a bit about that, I think, in our last hearing and at some of the staff briefings, which sounds promising. Again, a biodegradable capsule. What is the progress that is being made in the Government's efforts in this regard?

Dr. ELDERS. Well, that product is continually being developed, and there is probably someone here who are really directly working on it, from the National Institutes of Health, who know more about it than I do. But it certainly sounds like a promising product. It is put in, usually lasts for a year or 2 years, it is biodegradable,

there is no problem with removal, and it has been shown in animal studies to be very effective. However, it is not available yet for the marketplace.

Chairman WYDEN. Maybe if we could take a moment, if one of your associates is dealing with caprinol, I would very much like to have this subcommittee briefed on that.

Dr. ELDERS. Let us get you the full amount of information, because I know some general things, but you know almost as much as I know about it.

Chairman WYDEN. Well, I particularly want to use the work that is going on in these Government labs to promote more competition, because if you start with the basic proposition that you have only got these two companies out there, and the people in the Third World, according to experts, have more contraceptive choices than we do, we have got to figure out a way to inject some alternatives into this marketplace, and also we will be interested in the Department's approach to maintaining licensing control with respect to these products. If the Government is doing the heavy lifting, we have got to explain it to our taxpayers.

Dr. ELDERS. I think the Secretary and the Assistant Secretary are certainly working on this issue with the NIH to try and address the issues that you are bringing up.

Chairman WYDEN. Now, we understand that the Norplant Foundation supplies Norplant kits to physicians but not to nurse practitioners or other health professionals. That seems very unfortunate. Particularly because you are an expert in the field, I would be interested in knowing whether nurse practitioners often do insert contraceptive devices?

Dr. ELDERS. Well, certainly in the Arkansas Department of Health, and I think in many others, I know the Texas Department of Health, and I don't know about the whole country, but I know nurse practitioners do a lot of the insertion. They are very well trained, they have been trained by the Norplant Co. But like all drugs, we require physicians to order drugs in this country, and so it would have to be ordered by physicians in order for the company to even dispense it.

This does not mean that the physician would have to insert it, but the nurse practitioner could insert it under the — when I say supervision, that does not mean that the doctor has to be there, but the physician has to sign for accepting the drug.

Chairman WYDEN. So in your view, it would be acceptable for other health care professionals, possibly a nurse practitioner, a physician's assistant, a certified nurse midwife, to also be involved in supplying these, implanting these kits?

Dr. ELDERS. They are doing it all over the country already, so I certainly support that.

Chairman WYDEN. Wouldn't a larger role for these kinds of health professionals also be an opportunity to further lower the price, because my sense is that a lot of these health professionals that I am talking about, physicians' assistants, nurse practitioners, their rates, their fees are not as high as physicians, so if Wyeth were to recognize the realities of what we need to do here, they could have more professionals involved in the field and lower the price, and they can do that right now; couldn't they?

Dr. ELDERS. Well, I think, as I said, many nurse practitioners, nurse midwives, physicians' assistants are putting these in right now, certainly in our public health clinics. You notice that most of them are paid for by Medicaid because of that kind of narrow window that we have, so — and their rate is fixed, whether it is a physician's assistant or nurse practitioner, or whomever — and I think our rate in Arkansas was $85 for putting it in and $85 for taking it out. Obviously, if a physician puts it in or ob/gyn person, sometimes it is more expensive than that.

Chairman WYDEN. Certainly in the context of national health reform, and I think Mr. Andrews' point was very solid, as we look to new policies, at a minimum we ought to make sure that these kinds of health professionals could play a broader role than Wyeth is willing to let these folks play, and lower the price.

Dr. ELDERS. I think Wyeth is really just dealing with selling the drug. A physician can order or sign for 1,000 kits, but they do not have to put them in themselves, and nurse practitioners, physician assistants, nurse midwives are presently putting them in in many States across the country.

Chairman WYDEN. I agree with that. I think we both know that of course pharmaceutical firms send messages in terms of their supply practices. What I am interested in is having them send a different message and any message that can help lower the cost, and to me one way to do it is to expand the role of these other professionals. We will be interested in working with you on that as part of the national health reform.

Now, Dr. Haseltine, the Director of the Center for Population Research, testified before the subcommittee that she was going to be working on the issue of public-sector pricing with respect to access to contraceptives. What is the status of Dr. Haseltine's work at this point and her efforts with your office?

Dr. ELDERS. It is my understanding that Dr. Haseltine has just recently gotten an assistant to work in this area, and we talked with her yesterday and we will certainly be working on this together.

Chairman WYDEN. Let me ask you what you think of Wyeth's justification to me for their high prices at the public clinics. Let me just read this to you. We were talking to the Wyeth people about the high price of Norplant.

They said: "If the product came to be seen simply as a product for public-sector clients and lower-income users, we knew it would not be well accepted anywhere."

I have to tell you, Dr. Elders, here is the advertising pitch that they are using for the United States, and I really find this kind of justification for pricing morally repugnant.

I want to see drug companies in our country make a reasonable profit. We have got a free enterprise system, and they ought to get cost plus a reasonable profit, but an elitist approach to pharmaceutical pricing like theirs, is one that I just find very offensive.

I would be interested in your reaction to how they justified their high prices to this subcommittee.

Dr. ELDERS. Mr. Chairman, we desperately need their product for all women, not just the very rich, but we need it for everybody, and I am bothered that it is so difficult for many of our poor

women to be able to afford this product. But yet, I am, in many ways, grateful to Wyeth for taking the risk to bring, to even make the product available to women in America, period, so you are really kind of between a rock and a hard place. Hopefully, we can expand this and, hopefully, we can keep working to try and convince Wyeth to be a good corporate citizen such that we can make this product more available to all women.

Chairman WYDEN. Do they have us over a barrel?

Dr. ELDERS. They have got the only long-acting injectable in town.

Chairman WYDEN. Well, that is my view. I think you are using your office just as it has to be used. There is no question that the company has the American people, particularly these family planning clinics, between a rock and a hard place, and we have tried everything to get them on a voluntary basis to recognize the desperate need.

In fact, I guess we have established this, your office has found evidence that there are waiting lists all over the country, isn't that correct, for these kinds of contraceptive services?

Dr. ELDERS. Well, it is my understanding that there had been waiting lists for the availability, and I know we had waiting lists in Arkansas.

Chairman WYDEN. That is what folks at home in Oregon tell me. I just hope through a combination of using the Government as a savvy shopper, not a price controller, not a micro manager, but using the Government as a savvy shopper, getting more alternatives out there through the research that you all are doing, and then finally Wyeth recognizing, as you have said, that they have got to be a good corporate citizen, that we can deal with this issue. Because to me, getting good quality, affordable contraceptives available in our country is the way that we bring together the point that Congressman Combest has made about individual responsibility, a point that I very much agree with, and also the point that Mr. Andrews has made; that women must have these products, and it is not right that they are denied.

You have been very helpful to this subcommittee, and we appreciate that.

I think my colleague has an additional question.

We welcome you back.

Mr. COMBEST. Mr. Chairman, thank you. I became aware of this after.

Dr. Elders, you may not know the answer to this, but I understand that Depo Provera and Norplant are both neither under patent any longer, and yet there are no generic drugs similar, companies making generic contraceptives. Do you have any idea why in any of your discussions with individuals about availability, why there are no generics?

Dr. ELDERS. Mr. Combest, I really do not know. I thought that Norplant still had a while to go on their patent, but I might be absolutely wrong on that. Depo Provera has been out there, as I said, for 32 years, so I am sure the patent would have expired by now.

Mr. COMBEST. This isn't really a question, this is maybe a little bit of a clarification. I want to make sure I did not leave a misimpression for the record, Mr. Chairman, in regard to the pric-

ing, I was using the pricing from the testimony earlier of average of $18 to $23. I think it has been referred to kind of like in the United States, it is $350, and outside everywhere else it is $23, which is not the case.

From what I understand, the extremely low price of the $18 to $23 range is a price that is a foreign manufacturer has made in agreement with the Population Council and makes available to public-sector agencies in a few developing countries. The United Kingdom, for example, I understand at today's exchange rate would be about $265, and so it is not like everywhere outside the United States the price is at $23. I didn't want to leave the misimpression that that is the way it was everywhere else.

Also, one other thing that came up during the Chairman's questions. I thought it was a very good point; I think there are a lot of other areas we are going to have to delve into on the whole issue of health care, there are a lot of services in this country that are required or that are performed basically because of liability potential, and I am wondering if the insertion of the device of Norplant, having to initially come to a physician, and even though a nurse practitioner may be able to do it, if some of that could be done easier and less expensive but still very safely, if it were not for some type of a liability question. Do you know from a physician's standpoint, Dr. Elders, whether or not there is any concern about a liability problem?

Dr. ELDERS. I think for every procedure that a physician does, there is some risk, and so I think that we can't just say that, no, there is no risk, because we know there is some risk. If the physician ordered it, even though a nurse practitioner inserted it under their supervision, well, then, they do bear some risk.

Mr. COMBEST. Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague. I think he is touching on an important issue.

Of course, the $23 price is out there because the taxpayers are subsidizing it, the taxpayers through the AID Program subsidize it. So, we have a bizarre situation in our country where women wait in lines at family planning programs across the country and they can't get it, and women around the world can get it for a small fraction of the price. It doesn't get more exasperating, as far as I am concerned, in terms of a pricing predicament for the public.

Our understanding, Dr. Elders, is that there is a bit of time left on the Norplant patent. But the gentleman from Texas is absolutely right, I mean, developing drugs is a risky business. I am one who voted for product liability reform in another committee I serve, and so we want companies to understand that there is an effort to address their concerns.

At the same time, the taxpayers put huge sums into developing a drug, it costs much less overseas than it does here, and we still can't get the Wyeth Company to get interested in some sort of break for these public programs.

We have got to persevere — and I want you to know that I am going to stay with this until we get it done, because this is a way to really address many of the needs of women of this country, particularly low-income women. With your good offices and working together, we are going to turn this around.

Look forward to working with you.

Dr. ELDERS. Thank you, Mr. Chairman, and the subcommittee, thanks for this hearing.

Chairman WYDEN. We will excuse you at this time.

Our next set of witnesses, Catleen Decriscio, Norplant user from Altoona, Pennsylvania; Marian Petroski, executive director, Family Planning Center of Altoona; Judith DeSarno, president of National Family Planning and Reproductive Health Association; Lisa Kaeser, senior public policy associate of the Alan Guttmacher Institute.

If you all will come forward.

You all are on your feet so you are obviously up on the rules of this subcommittee.

I gather none of you have any objection to being sworn as a witness?

Please raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. We thank all of you for your participation and your attendance. We are going to make your prepared remarks a part of the hearing record in their entirety.

What we would like, I know it is always hard to do this, ask you to just talk to us for 5 minutes or so. Your prepared remarks will be part of the record.

I hope I have not done violence to pronouncing your names.

Is it Decriscio?

Thank you. You are very good to come, and we really appreciate your attendance and welcome, please proceed.

TESTIMONY OF CATLEEN DECRISCIO, NORPLANT RECIPIENT, ALTOONA, PENNSYLVANIA

Ms. DECRISCIO. Thank you.

Mr. Chairman, members of this subcommittee, my name is Catleen Decriscio, I am a 27-year-old mother of two children. I live in Altoona, Pennsylvania, and am the recipient of a grant which enabled me to receive Norplant in December of 1993.

I am very pleased with Norplant and would recommend it to other people, and I have; but most can't afford the cost because they don't have insurance. I learned about Norplant at the Family Planning Center of Altoona Hospital when my nurse practitioner at the center showed me a pamphlet on birth control options.

I don't have health insurance or any other way to pay for expensive birth control. At first Norplant didn't look like an option because I work part-time and my husband and I don't have health insurance. We also don't qualify for Medicaid because between the two of us our income is considered too high.

There is no way that my husband and I can afford the $515 for Norplant without insurance coverage or a grant; $515 is more than our house and car payment.

My nurse practitioner told me that if I really did want Norplant, it might be possible for me to receive Norplant through a grant, although the chances for this I was told were very slim.

There are several sources for Norplant grants. I received a Norplant kit from the Norplant Foundation. The insertion fee, however, was not covered by the Foundation. The Family Health Coun-

cil of Pennsylvania donated the money for the insertion procedure. I filled out the forms in October and in mid-December I was finally granted the Norplant insertion free of charge.

I was pleased to have Norplant. I can feel protected for 5 years, and I can have it removed at any time. I have no adverse side effects or anything of that sort. I feel empowered by the ability to decide when and whether I want to have another child.

Norplant has made a big difference for me. I definitely prefer it over other birth control methods. Previously, I have used condoms and the pill, but I wanted a more long-term contraceptive with fewer side effects. I got headaches and mood swings from the pill and it was hard for me to remember to take them every day.

My family also has a history of breast cancer and this made me feel uncomfortable about taking the pill. If I didn't have Norplant now, I would have continued with the pill even though I wouldn't have been comfortable with it, and the potential health risks.

I was one of the lucky women who actually did receive a grant from Norplant. Norplant to me is such a great birth control option for women, it is a shame that it is not available to all of us. I recommend Norplant to my friends, but few can pay to have it inserted.

For a woman such as myself and others like me who work part-time, raise children, and are not interested in more children for the time being, Norplant is an ideal contraceptive. The problem is most of us can't afford it.

I am appalled at Dr. Deitch of Wyeth-Ayerst who justifies the high price of Norplant by saying it will not be seen merely as a poor woman's method of birth control. Birth control should be available to all women, regardless of their income level. People like me are left out of the system because we are caught between the benefit packages of two classes, and we don't fit into either.

I was very lucky to receive a grant, but don't let the existence of the Norplant Foundation fool you into thinking that Norplant reaches many middle- and low-income women. My situation is unique and not many women are as fortunate as I was.

In closing, Congressman Wyden, I appreciate all the work you and your subcommittee have done. I strongly urge Wyeth-Ayerst to reconsider and reduce the price of Norplant. It is an outstanding contraceptive, and economics should not bar women from utilizing it.

Thank you.

Chairman WYDEN. Well, thank you. You have said it very, very well. It is never easy to talk about things that are so personal.

I will have a few questions in a moment, but you really said it very well. I sure appreciate your coming to Washington and telling your story.

Ms. DECRISCIO. You are welcome.

[Ms. Decriscio's statement may be found in the appendix.]

Chairman WYDEN. Ms. Petroski, welcome.

TESTIMONY OF MARIAN PETROSKI, EXECUTIVE DIRECTOR, FAMILY PLANNING CENTER OF ALTOONA HOSPITAL

Ms. PETROSKI. Good morning, Chairman Wyden and members of the subcommittee. I am Marian Petroski, I am the executive direc-

tor of the Altoona Hospital Family Planning Program, Altoona, Pennsylvania. I am delighted to have this opportunity this morning to speak before you regarding my clinic's experience with Norplant.

At our family planning program we serve over 4,000 women annually. We provide comprehensive reproductive health care to anyone who walks through our door, regardless of income. This mission has become harder and harder to fulfill in the recent years.

My clinic is located in Altoona, which is a small industrial city in central Pennsylvania. Our center is the only family planning provider in Blair County, which is a largely rural county about 2 hours from Pittsburgh.

We have been hard hit by the industrial declines of the 1980's, especially with the decline of the rail industry, and we continue to have very high unemployment rates that exceed the national average.

In Altoona itself and the surrounding Blair County area, the numbers of uninsured, underinsured and what we call the "working poor" have continued to grow and many of them have elected to come to us to fill the gaps in their health care services.

We have made Norplant available in our clinic since 1992. To date, we have inserted 200 Norplants. Out of those 200, only 2 have been paid for by full-fee clients, remembering that under Title X we have to have a full-fee schedule at 200 percent of poverty, so we have only had two clients who have been able to pay that full fee, which is 1 percent.

Of the remaining 198, almost all have been paid for by Medicaid. Even though only 28 percent of our patients are Medicaid, the remaining 198 have been funded by Medicaid. A very few lucky women, about 30, have been able to obtain Norplant for free. Twenty of these women were able to get Norplant kits made available to the doctors at our clinic when we first began offering Norplant.

Initially, we were told by Wyeth that there was a physician lifetime limit of 10 free kits, which we quickly ran through. I now understand that this has been changed to an annual limit of 10 kits, and this revision is an improvement, but it still falls short of supplying an adequate number of kits, and this is in part because the foundation will supply kits only to physicians affiliated with the clinic rather than to the nurse practitioners who provide the bulk of the services at most family planning clinics.

We are fortunate, we have two physicians, so we have been able to get 20 kits. But you could be in Harrisburg, have 7,000 patients, one physician, get 10 kits for 7,000 patients.

In addition, there are numerous administrative hurdles that both the physicians and the patients must go through before the Norplant Foundation makes the kit available. Therefore, it is not surprising that of the 200 Norplant kits that we have inserted, that only 10 percent were donated by the Norplant Foundation.

In addition to the 20 from Norplant, we have been able to obtain 10 kits from a special subsidy from the Family Health Council of Central Pennsylvania which is the Title X grantee for our area. But even when the Norplant Foundation donates the kits, there are so many attendant expenses, it is only the kit itself that is free, thus for even so-called "free kit," the kits donated by the Norplant Foundation for which Medicaid pays a little over $300, we absorb $200,

a Title X clinic absorbs over $200 in costs associated with the full Gyn exam, the insertion, the follow-up visit and the removal.

So, for example, we have already for the 200 kits that we have put in, we have absorbed over $4,000 worth of costs. Even though the kit has been free, we still have $4,000; so you can understand why given our extremely tight operating budget it is impossible for us to absorb the $500 cost for individuals who cannot get the kit either donated by the Norplant Foundation or who are not eligible for Medicaid and still continue to provide reproductive health care for the remainder of our patients. There is just no way that we can have judicious budgeting that will make up for that gap of money.

Mr. Wyden, as I have indicated, it is virtually impossible for a poor woman to get Norplant at my clinic if she is not eligible for medical assistance. Medicaid covers only one segment of the poor woman who could conceivably benefit from this product. For women who are below 100 percent of poverty level who are not eligible for Medicaid because they are trying to avoid their first pregnancy, there are limited resources available.

There is an additional group of poor women with incomes above 175 percent of poverty, which is the cutoff for eligibility for the few free Norplants we are able to insert, who cannot afford the $500 price tag. Plus, there are many women who by almost any definition would be considered poor, and what we call the working poor for whom this is the optimal method of birth control who do not have access to Norplant.

While the demand for Norplant has leveled off somewhat because of the introduction of Depo Provera, we are still in the uncomfortable position of forcing many women to elect their second choice method. Because of Norplant's high cost, some women leave our clinic with no method of birth control, they may return down the road perhaps later for Norplant or some other method.

Other women, however, fall through the cracks, they may be transients, they may seek help elsewhere, and some become pregnant. I personally know of two women at our clinic who became pregnant waiting to receive Norplant through some sort of a subsidy program.

We just cannot afford to miss these opportunities to provide needed contraceptive services, not to mention essential primary and preventive care. Our inability to provide Norplant to all comers is a problem, especially for young women we see who are, in many instances, ideal candidates for Norplant.

For sexually active young teens and young women who are seeking to postpone pregnancy for childbearing reasons, to attend school or to obtain other career training, we do a real disservice to them by effectively limiting their contraceptive options. We also know that if women are unable to obtain the contraceptive method that is their first choice, they are less likely to use their second choice method consistently and correctly, and waiting until they can save the $500 to pay the up-front costs of Norplant puts many at risk for unintended pregnancies.

We cannot afford to lose these women when they seek to make responsible choices, nor can we afford to turn away poor women who have no other source for confidential reproductive health care.

I can't emphasize enough the importance of the confidentiality, something guaranteed in all Title X clinics.

The high cost of Norplant puts a clinic staff in an untenable position when attempting to provide nondirective counseling to women about all contraceptive options because in reality they are not equally available due to the cost. The Title X guidelines are very clear that all options must be presented to clients, and they are. However, the program does not provide the level of funding that enables us to provide all services to all clients.

At our clinic our policy, if a non-Medicaid eligible woman requests Norplant and funding is not available, it is generally to place her on a waiting list or refer her to another clinic where the device may theoretically be available. However, this course of action is not realistic in light of the true availability, because the reality is, Mr. Chairman, that we cannot offer women real alternatives. The closest referral site is over an hour away, and I know for a fact that this clinic, having worked in it, is in no better position to provide Norplant to poor women than we are.

The truth is the women we serve do not understand why this product costs so much, and we share that confusion, so we are not able to shed much light or offer satisfactory explanation to our clients. As you heard Ms. Decriscio address, $500 pays a month's rent and the grocery bills. Clearly, there is no adequate justification for forcing women to choose between the necessities of birth control on the one hand and the food and roof over your head on the other.

Mr. Chairman, you and I know that this is a choice that no woman should ever have to make. However, I keep returning to the bottom line because this is what ultimately counts. Because the State Medicaid Program pays $500 for a Norplant insertion, we are able to provide the service, but we have created a two-tiered system, and clearly this is not the message we want to be sending.

However, at the same time, my clinics cannot absorb the tremendous expense of Norplant for non-Medicaid patients who are too poor to pay the entire costs of the product. For some women the introduction of Depo Provera has been the answer to the high up-front costs of Norplant. While the cost of Depo, $33 at our clinic, every 3 months, can be a significant one to women who are struggling to get by, it is far easier to come by than the $500 for Norplant.

Depo also necessities more frequent visits, clinic visits, which can be a problem in areas like ourselves which are rural and transportation becomes a problem for access for these women. The only way I can see to remedy the current situation is not to earmark special funds as the State of Pennsylvania has considered doing, not making a precious few free kits available via the Norplant Foundation and pretend that this translates into access for poor women, or to have women using a method that they deem less than optimal.

Instead, it is imperative to make Norplant and Depo as well, available to public clinics such as the Family Planning Center at a greatly reduced price so we can give patients what they really need and what they really want, which is immediate access to safe, affordable and long-term, long-lasting contraceptives. The kits provided by the Norplant Foundation are but a drop in the bucket

given our need, and there is no significant discount at all available for Depo Provera.

The Title X, Title XX, and Title V dollars that we have available for family planning services are always in short supply, and have not kept pace with the increasing costs of contraceptive drugs and devices. In 1993 alone, our costs at our clinic for overall costs of pharmaceuticals escalated by over 20 percent, in part fueled by the high cost of Norplant.

Mr. Wyden, as clinic director, I know we cannot afford to let our patients fall through the cracks. I also know that as a country we cannot afford to have women's choices artificially constrained by pricing policies which allow pharmaceutical companies to reap profits at the expense of poor women. I urge you to take whatever action is necessary to ensure that Norplant be available at public clinics at greatly reduced price.

Thank you.

Chairman WYDEN. Thank you very much, excellent statement. We will have some questions in a moment.

[Ms. Petroski's statement may be found in the appendix.]

TESTIMONY OF JUDITH M. DeSARNO, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, NFPRHA, WASHINGTON, DC

Chairman WYDEN. Ms. DeSarno, it is good to have you back before this subcommittee. We appreciate the good work that you do. Please proceed with your testimony.

Ms. DESARNO. Thank you, Mr. Chairman.

Mr. Chairman, my name is Judith DeSarno, and as president of the National Family Planning and Reproductive Health Association, NFPRHA, it is an honor to appear again before you this morning.

NFPRHA is a nonprofit membership organization which was founded to expand and improve on the delivery of voluntary reproductive health care to all women, and as such we represent the entire community of family planning providers in the country, including virtually all of the Title X grantees.

I appreciate the opportunity to again address this subcommittee. When I appeared before you last November, I outlined in detail the efforts that NFPRHA has made to obtain a deeply discounted price for Norplant for the Title X clinic system. I explained that the clinics receive oral contraceptives at an average price of 65 cents a cycle. Those pills cost $21 to $25 at your local drug store, but that the cost of the Norplant device remains a very high $300 for the PHS-funded clinics.

I described the steps we have taken to try and work with Wyeth-Ayerst to obtain Norplant at a deeply discounted or nominal price, standing practice with their birth control pills, all to no avail. That has not changed. We have the same problem with Depo Provera, although the Upjohn Co. has indicated in recent weeks that they are willing to open discussions with NFPRHA about the possibility of a lower price for Depo in the publicly funded clinics.

In the meantime, the situation leaves our clinic staff completely exasperated, wreaks havoc with our clinic's financial viability and effectively discriminates against our patients.

You have heard of that experience now firsthand. I would like to focus my testimony on the overarching public policy which governs today's discussion.

Mr. Chairman, Title X clinics are required to offer all contraceptive options to our clients, and our clinicians are extremely conscientious about taking time with each and every woman to determine the option which best suits her needs.

Most of our clients are familiar with and request oral contraceptives, which we provide free for women at 100 percent or below of poverty, and for a very modest fee for women between 100 and 250 percent of poverty. Again, the average cost of a cycle of oral contraceptives to our clinics is 65 cents, well below the definition of a nominally priced drug.

A completely different situation faces the Title clinics with respect to the two newest contraceptives, Norplant and Depo Provera, and in many cases, they represent a superior method for our clients. In addition to requesting Norplant which costs our clinics $300 per kit, our clients are increasingly requesting Depo Provera, which cost our clinics $21.95 for a 3-month injection.

Our clinics, however, can only respond to a fixed number of requests for Norplant or Depo because there is no public price for either. The cost of purchasing these contraceptive methods alone, without factoring the costs of providing the implants or injections, means that it is virtually impossible to respond to the demand for these options without dramatically decreasing the number of clients we currently serve.

Scaling back the number of women we serve when there are already so many not receiving any services is simply unconscionable. In short, Mr. Chairman, the Title X clinics are grossly underfunded to begin with, are being forced to deny a woman her first choice of contraceptive, place her on a waiting list, again to try to juggle an already stretched budget and lament our inability to afford to offer Norplant or Depo Provera to each of our clients.

In discussions, Mr. Chairman, we have explored possible solutions to this dilemma. Current law permits the Federal Government to negotiate bulk purchasing on behalf of public health entities.

However, the office at HHS in charge of this authority is not fully operational. Even if it were, the true obstacle, as you have identified, in negotiating a nominal price, is competition. Each of these is a sole-source product. There is simply no incentive for either pharmaceutical company to offer a public price. Any real solution right now seems very far away.

One solution which may be worth exploring is providing grants to small pharmaceutical manufacturers to develop contraceptive drugs or devices. As part of the contract for receiving Federal assistance and financing research and development, manufacturers would have to make low prices available to publicly funded clinics. Congress could also pass legislation to require a similar arrangement if the R&D is partially financed by public funds such as the case of Norplant.

The Contraceptive Development Branch at the National Institutes of Child and Human Development might be the appropriate governmental Agency should Congress decide to conduct the R&D itself. I note that both Norplant and Depo have gone off patent and perhaps the first place to begin is by giving a grant to companies willing to produce a generic substitute.

Given current budget constraints, I do not anticipate that Congress will be able to provide the Title X clinics with sufficient moneys to purchase adequate numbers of Norplant kits or Depo Provera injections without a publicly discounted price. To be perfectly candid, Mr. Chairman, any additional funds received by Title X clinics should really be used to expand our services, restore our outreach and education programs, and reach those individuals who are in need of our services but who are currently receiving no care.

I find it very distressing that during your subcommittee's last hearing on contraceptive drug pricing, the manufacturer of Norplant stated that one of the reasons why the price of this product was set and remains so high is to ensure that it will not be seen merely as a poor woman's contraceptive option.

Dr. Mark Deitch, a Wyeth-Ayerst vice president, stated that if the product came to be seen as a product for public-sector clients and low-income users that the company knew it would not be well accepted anywhere. My reaction to this statement is, quite frankly, utter contempt. But far from distancing itself from reaping profits on the use of Norplant by poor women, Wyeth-Ayerst actively sought Medicaid approval in all 50 States.

Further, Wyeth-Ayerst supports State legislatures throughout the country earmarking funds for the purchase of Norplant kits, and I can assure you, Mr. Chairman, the States are not getting any special deal. They are paying $300 per kit, just like the rest of the public-supported health centers. So, on the one hand, the company doesn't want to associate itself with low-income users because to do so might undermine its marketing plan, and on the other hand, the company is promoting its product to every State health director around the country. This is a true dilemma for us.

NFPRHA obviously wants every poor woman to have the choice of this contraceptive available to her. However, for this company to refuse to offer a deeply discounted public prices using the marketing excuse that they don't want it to be seen as a "poor woman's contraceptive," only to turn around and lobby State legislatures to purchase the drug at full price is disgraceful. They are making a small fortune serving poor women through Medicaid and through State-funded earmarked programs.

States should refuse to earmark funds for a particular contraceptive unless that company is offering a deeply discounted price. Further, those States wishing to earmark precious health care dollars for family planning should leave it to the family planning clinics to decide with their patients which is the best contraceptive choice.

I hope I have made some suggestions that might be helpful to the subcommittee in its quest for a solution to reducing the cost of new contraceptive methods for all women in the country. I commend you and your staff for your commitment to searching for ways to assure that the full range of reproductive health care is available without regard to one's ability to pay.

We look forward to continuing to work with you in the coming months, and I hope you will call upon NFPRHA if we can be of any assistance.

Again, thank you for extending the invitation this morning.

[Ms. DeSarno's statement may be found in the appendix.]

Chairman WYDEN. Well, thank you, Ms. DeSarno.

I think you have heard me say that I am not a real wild fan of the marketing and pricing strategy that is being employed by Wyeth on this matter as well. I will tell you, having worked in this field for about 20 years, first with the Gray Panthers on pharmaceutical issues on the Health Subcommittee, I have never heard this kind of unique thesis offered as a basis for marketing and pricing, and we intend to stay with this matter as we talk to Dr. Elders.

Ms. DESARNO. We appreciate your leadership.

Chairman WYDEN. Staff informs me that Norplant still has a little bit of time left on the patent, and we are going to try to clarify this one way or another at the end of the hearing.

Ms. DESARNO. For many drugs going off patent, however, companies can be ready virtually the next day with a generic, so the idea of providing some small R&D grants now I think is even more timely, because the pharmaceutical could in fact, be ready the day after it goes off market. I think it may in fact, be the rods, the covering rods that haven't yet gone completely off patent.

Chairman WYDEN. Your point and a suggestion as a way to again inject more competition into this field, I think is an excellent one. I am going to have some questions for you in a moment. We will clarify this matter with respect to the patent as well.

Ms. Kaeser, you have done a superb study. I had a chance to read it thoroughly last night, and really appreciate the outstanding work being done at Guttmacher.

Please proceed with your presentation.

TESTIMONY OF LISA KAESER, SENIOR PUBLIC POLICY ASSOCIATE, ALAN GUTTMACHER INSTITUTE, WASHINGTON, DC

Ms. KAESER. Thank you.

Good morning, Mr. Chairman. I am Lisa Kaeser, I am a senior public policy associate at the Alan Guttmacher Institute, a not-for-profit corporation for reproductive hgealth research, public policy, analysis, and education.

On behalf of AGI's president, Jeannie Rosoff, we appreciate the opportunity to share with the subcommittee the results of three recently completed studies, two of which pertain specifically to Norplant and the third on private health insurance coverage in the United States for contraception.

As you recall, Norplant first became available on the U.S. market in February of 1991, the first major new method in years. However, it took many States a period of time before they were able to make the method available using public-sector funds. The first survey assessed levels of public funding spent on Norplant in 1992 and reviewed the development of policies under which those funds were made available.

Each State agency treats family planning services differently. Medicaid reimburses for services, whereas the State health depart-

ments actually provide services, so we chose to survey all of the State Medicaid health and welfare agencies, plus the 12 area offices of the Indian Health Service. Our findings included the following facts:

In 1992, nearly 10 percent in public funds allocated for reversible contraceptive services in the United States, approximately $61 million, were spent to provide the implant to low- and moderate-income women. That year, public funds paid for over 150,000 insertions and nearly 6,500 removals. Most of this was Federal funding. Only 9 States committed monies from their own coffers.

Medicaid was the single largest source of public funding; 94 percent of all Federal funds spent on Norplant and 84 percent of all public funds were provided by Medicaid. Although the Title X Program is the only Federal program devoted solely to providing family planning services, the $1.8 million in Title X funds spent in 1992 represents a mere 3 percent of public funds spent on Norplant.

We also looked at State administrative policies that might encourage use or limit the availability of this new method. Forty-one State health departments stated that they do make Norplant available at least in some of the clinics they support, and of these, 27 had a policy requiring that clinics must make the implant available to all clients who are eligible for the clinic's other services.

On the other hand, 13 State Medicaid agencies reported policies that limit the number of Norplant insertions they will pay for in any given time period. Eight of these limit coverage to once every 5 years.

Further, no State Medicaid agency indicated that it would cover removals among implant users who become ineligible for Medicaid while the implant is still in place. This is a situation in which many women find themselves who have become eligible for Medicaid only during the postpartum period.

One Medicaid agency, in Oklahoma, reported a policy that restricts coverage of removals prior to the end of 5 years for medical reasons only. What that means is that if a Medicaid-eligible woman chooses to have the implant removed for any other reason, such as choosing to become pregnant, or the side effects are unbearable for her, she must pay for the removal herself.

In contrast to Medicaid agencies, eight health departments responded that they did have policies ensuring subsidized removals for women who become ineligible for Medicaid. None of the agencies reported that for insertion women must meet any marital status criteria or criteria involving the number of children they have, nor did they report any monetary incentives to either promote the use of Norplant or to encourage keeping it in once they had it.

However, two States do require parental consent before adolescents may receive Norplant — Utah and South Carolina. Utah has a State law requiring parental consent for all contraceptives provided to minors. South Carolina's is based on an Attorney General's opinion that says that since Norplant involves minor surgery, there must be parental consent.

While Utah's State and local health departments have been ineligible for the past 10 years to receive Title X funding, South Caroli-

na's public agencies continue to receive it. Nor are the teens in these two States the only ones who face this type of restriction.

Our second study of family planning clinic providers, as opposed to the State agencies, found that fully a quarter of these providers enforce a parental consent requirement for Norplant but are under no State-level mandate to do so. I want to make it very clear here that because of its long-term effectiveness, providers routinely encourage adolescents interested in Norplant to discuss it with their parents. However, a teenager who is reluctant to talk about contraception with her parents may find that implants are off limits for her.

This second study looked at the ability of family planning providers to make Norplant available to their clients as well as the practices and policies adopted by these providers. A sample of over 600 publicly funded providers were surveyed, including hospitals, health department clinics, Planned Parenthood affiliates and others; by September 1992, nearly 2 years after Norplant came on to the U.S. market, only 40 percent of family planning providers were able to offer the implant to their clients.

Hospital-based clinics and Planned Parenthood affiliates were the ones that moved most quickly to initiate implant services. Among the providers that had not yet begun to offer implants, the lack of trained clinicians and cost considerations were cited as the paramount reasons. Sixty percent stated that their staff had not been trained to insert or remove implants; 39 percent reported that the clinic itself could not afford implants; and 22 percent claimed that their clients could not afford implants.

If a woman attending a family planning clinic is not a Medicaid recipient or does not have private insurance that will cover both the device and its insertion, she may face a variety of pricing policies that vary widely from clinic to clinic. Thirty-three percent of the providers surveyed reported that fixed fees are charged to all women desiring implants who do not have other coverage. Pricing policies were found to vary by provider type, with hospitals being the least likely, and health department clinics being the most likely to offer Norplant using sliding fee scales.

The median fees charged for insertion by providers who use a sliding scale, range from $2 to $485, and the median fee charged by providers with fixed fees is $500. The corresponding typical charge to have implants removed ranges between nothing and $111 for providers with sliding fee scales, and is $100 for providers with fixed fees. Fully 63 percent of all implants provided at family planning clinics were paid for through the Medicaid Program.

The results of these two studies demonstrate the primacy of Medicaid in providing access to Norplant among poor women, even while that access remains uneven. A woman on Medicaid attending a family planning clinic is 12 times more likely to be provided Norplant than is a non-Medicaid eligible woman attending the same family planning clinic.

Still, the ability to choose Norplant is not completely assured, even to Medicaid recipients, since removals are not covered by any State Medicaid agency if a woman becomes ineligible during the life of the method.

Further, funding provided through Title X and other Federal and State programs intended to increase access to family planning services has decreased precipitously over the last decade. Consequently, funds are being allocated at the clinic level to provide services to the greatest number of women at the lowest possible cost. This strategy could lead, however, to an overdependence on methods such as the pill, which do not require a long-term investment and which is usually, as you have heard, available to clinics at a deep discount.

Ms. KAESER. Other issues of access and quality of care play secondary but still important roles in making a new, unfamiliar method available to all women who wish to use it. Personnel policies, including who will be reimbursed for providing the contraceptive method, may often dictate which health care professionals will be able to insert or remove the device.

I know this question came up a little bit earlier with Dr. Elders. We found that in 13 States physicians are the only personnel eligible for Medicaid reimbursement. On the other hand, in 30 States nurse practitioners are also reimbursed; in 25 States and the District of Columbia, nurse midwives, and in 9 States, physicians' assistants.

However, 64 percent of hospital providers stated that physicians alone perform implant procedures. In contrast, 74 percent of Planned Parenthood affiliates reported using solely clinicians other than physicians to perform insertions.

Some women are dissatisfied with the method. For some, the circumstances of their lives change. A few may have medical problems. In each case the woman must be assured that the provider is willing, educated and able to remove the implants.

Up to this point we have focused on the provision of Norplant in the public sector for women eligible for Medicaid. However, it cannot be assumed that women who have private insurance coverage are in a significantly better position to get implants.

Chairman WYDEN. Let me interrupt a second. That is the chart that is in your report, isn't it?

Ms. KAESER. That is right. Data recently released from our recent study of private health insurance coverage with regard to reproductive health services found that the historic tradition of covering surgical services remains very strong.

Since reproductive health care consists mostly of preventive health care services, the implications are troubling, especially as the Nation considers health care reform. Sterilization, as can you see from this chart, the most common form of contraception in the United States today, is routinely covered by 85 percent of all types of typical insurance policies. I should point out here that this chart refers to the large group plans only, representing over 100.

Coverage of abortion follows much the same pattern. Two-thirds of all the policies included in our survey routinely cover abortion, which most people find very surprising.

In sharp contrast but in line with this traditional bias of health insurance, coverage of reversible contraception is uneven at best. None of the five reversible methods included in our surveys, IUD's, diaphragms, Norplant, Depo Provera and oral contraceptives, is routinely covered by more than 40 percent of typical plans.

Half of the large group plans typically do not cover any method at all and only 15 percent cover all five methods. It is remarkable that oral contraceptives are covered by only one-third of the large group plans. This is not the result of a general failure to cover prescription drugs. While 97 percent of large group plans typically cover prescription drugs, two-thirds of the plans do not cover the pill.

Along these same lines, while over 90 percent of large group plans cover medical devices in general, more than 80 percent of these plans do not cover IUD's or diaphragms, and three quarters do not cover Norplant. Only 24 percent of plans routinely cover all three components of Norplant, the device, insertion and removals. In addition, only 22 percent of large group plans cover contraceptive counseling, which is critical for the satisfied use of Norplant.

The next chart relates to health maintenance organizations. The picture is significantly better for HMO's. Only 7 percent provide no contraceptive coverage at all. The use of Norplant is less complete, only 46 percent, than for the other reversible contraceptives. Still, contraceptive counseling is covered by 90 percent of HMO's.

In this study about three quarters of the women who have some form of private insurance coverage are not covered for Norplant.

Clearly there is an ongoing demand for women and their partners at all socioeconomic levels for a broader range of methods and services. At a minimum, as a matter of national policy, we should make all medically approved and effective methods available to everyone who wishes to use them. Clearly this is not the case now, which has been starkly demonstrated by the introduction of Norplant to the U.S. market.

Our studies show that only poor women who are eligible for Medicaid, women who are not only covered by private insurance but fall under the minority of plans that do cover Norplant, and those women who are able to afford the up front cost of the implant themselves are actually able to obtain it.

Given current funding and pricing policies few women will be likely to obtain and use Norplant. Title X family planning clinics, were created to increase access of contraception available to anyone who wished to avail themselves of their services. The fact that other methods are available at lower prices places clinics in the untenable position of subsidizing services for one woman who wants to use Norplant at the expense of many women who may want to use the pill.

The issue of cost is the deciding factor in terms of which methods are chosen.

While the Norplant situation is an extreme example, cost factors affect the other highly effective long term methods as well. I would also like to mention IUD's. That is a method that is effective for 8 years, and it is even less expensive over that period than Norplant or Depo Provera.

Unless Norplant and the other methods are made available at public sector price that allow clinics to offer them, or unless Title X funding is increased to a sufficiently high level that allows clinics to provide all methods, few low and moderate income women will have real choice of contraceptives. Yet the cold reality is that funding for Title X is unlikely to be increased to a sufficient level.

Only when individuals are assured of making their choices are they likely to be as successful contraceptors as they would like to be. Consequently all women and their partners must be provided the opportunity to easily obtain and to use contraception along with complete freedom regarding which of the methods they choose. To accomplish this family planning services should be included among basic preventive services provided under our health care system without copayments, and all methods must be covered.

Thank you very much.

[Ms. Kaeser's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much.

I want to commend all of you for the Guttmacher study, which is excellent. It brings up to date our knowledge in this field. We appreciate the good work.

Ms. DeSarno, let me ask you one question. I understand Wyeth has recently proposed a new Norplant purchase option, something involving a credit card or something like that. Is this correct?

Ms. DESARNO. Wyeth has begun making calls to the Title X system wanting to come in and talk about the cost effectiveness of Norplant. But they add some new creative ideas on how to make it affordable for poor women, and their new creative idea is to put it on a Visa or MasterCard, meaning you don't have to pay for it up front. Obviously most of our clients that we serve do not have Visa or MasterCards.

It is nothing to make it more affordable that you can charge it now, and pay interest, of course.

Chairman WYDEN. That is my other concern, is that what this would do is create a situation where women in particular, based on all your testimony, are so desperate, and understandably so, then if they use this new Wyeth operation, put it on their credit card — I don't know what the interest charges are on Visa today, but I am sure they are way over 10 percent, aren't they?

Ms. DESARNO. I think they probably go as high as 18 on a yearly basis. But there are two other issues. One, many of our clinics do not in fact, accept credit cards. Second, many, many of our clients do not have credit and credit cards. But it really shows the continuing lack of understanding of this company of what we are talking about when we talk about opening a market to poor women. It is not Visa or MasterCard.

Chairman WYDEN. I am just floored. These folks just seem sort of unscathed by the idea of what is really going on out there among low-income women in this country. If this is the new option that has come about since November, we are just going to have to continue these hearings, and bring some folks in line with the reality of what you all are talking to us about.

But it is pretty clear that is not going to do it.

Ms. DESARNO. I want to really thank you again for having an additional hearing. So, often we have a hearing, statements are made, and then they sort of go away, the classic 15 minutes of attention to an issue. But the continued pressure and limelight is in fact, going to help us work out a solution. We greatly appreciate this.

Chairman WYDEN. The fight has just begun.

Ms. Petroski, what about your program? You are out there on the frontline; you run a program. Do your folks have credit cards? Is this something that is going to help people in Pennsylvania?

Ms. PETROSKI. I can only laugh. Obviously they do not have credit cards. That is not a viable option. We have a rather unique situation in that we have within our Title X grantee area, we have a significant proportion of medical assistance clients. So, in some sense we may actually be better off because we have a large number of clients who are getting the MA — getting it through MA, although I shudder to think what that means in terms of the State medical assistance program and the availability of dollars.

But we have a very large segment of the working poor. When the rail industry went out, what we have is many women coming to us seeking care through private physicians who can no longer afford that, and they are coming to us. There is no way they can afford the $515 we can collect to cover our insertion costs.

Even for those kits we have inserted to date, part of the Wyeth Foundation and Norplant Foundation guidelines are that you must provide it for 5 years. So, 5 years down the road we are going to still be bearing those costs. Our clients certainly don't have credit cards.

Chairman WYDEN. Ms. Decriscio, a question for you. Again, we really appreciate your coming. I focus especially today on women who are eligible for Medicaid, because it would seem to me to be especially important at a time when Congress is considering welfare reform, and we are sitting here watching these two camps, the so-called liberal camp and so-called conservative camp duke it out. I thought that making sure women had access to contraceptives would promote individual responsibility and at the same time give people the means to do it.

But you are in a special predicament. You are kind of in that Catch 22 of so many hard working Americans, I gather, where you don't qualify for Medicaid, but you have a family, things are tight, and it is hard to afford these health services you need. I gather what you are saying is if it hadn't been a rare luck of the draw, you just wouldn't have been able to get what you needed.

Ms. DECRISCIO. Right.

Chairman WYDEN. What would you have done if you couldn't have gotten Norplant?

Ms. DECRISCIO. I would have continued to use the pill for a while and then probably just not used anything, or my husband would have gone back to using condoms or something.

Chairman WYDEN. I gather the reason this was so important to you, and you wanted to have other options, is you had bad side effects with the pill?

Ms. DECRISCIO. I was moody and had real bad headaches and bad temper. I would fly off the handle right before that time, and my husband couldn't deal with it anymore either.

Chairman WYDEN. So in your opinion, if it hadn't been for the luck of the draw, and you hadn't had Norplant, what would have happened is the pricing structure that is employed here would have forced you back to health services that didn't work for you and caused you a problem?

Ms. DECRISCIO. Definitely.

Chairman WYDEN. What do other women in Altoona do in this kind of situation?

Ms. DECRISCIO. There is a couple that we know, her husband was telling her she should think about getting it but she said they couldn't afford it. They didn't say what their options were going to be or anything like that.

Chairman WYDEN. What about the removal situation? What is the status or what have you been informed about with respect to removal and your right to have it removed and the cost and this kind of thing?

Ms. DECRISCIO. I can have it removed at any time I choose, at the end of the 5 years, and I don't have to pay for it at all.

Chairman WYDEN. But you want Norplant because it works, because you think it is good and it is a real contribution to your health care.

Ms. DECRISCIO. Yes.

Chairman WYDEN. The concern you have is price.

Ms. DECRISCIO. Yes.

Chairman WYDEN. Ms. Petroski, has Norplant limited the number of free kits that your programs have been able to get?

Ms. PETROSKI. As I indicated, when it first came out we were under the impression that each physician had a lifetime limit of 10 kits for us. We have two physicians affiliated with the clinics, so that gave us 20 kits. They since revised it and said that is 10 per year. That 10 per year is 20 between the two physicians. That does not begin to address the need for the working poor.

Chairman WYDEN. What are the implications with respect to Norplant supplying these kits to physicians rather than to nurse practitioners?

Ms. PETROSKI. Nurse practitioners at our facility provide 98 percent of the care that is rendered to the clients. So, obviously — and they do the insertion itself of the Norplant. Actually the physician names what it needed to get the kits. The practitioners do the inserts, they do the removals, they provide the care. So, it seems rather ludicrous to limit the free kits to the physicians who serve as medical directors.

Chairman WYDEN. Your sense would be that, again, expanding the pool of professionals involved here could help lower the cost as well? Having people like nurse practitioners, physician assistants involved more directly could help lower the cost——

Ms. PETROSKI. It does lower the cost to some extent already. For example, at our facility it would be $500 whereas perhaps for a private physician or other clinic, $700. So, it does lower it. But when the cost of the kit remains $365, that still becomes incumbent for us to charge a fee that is still untenable for the working poor.

Chairman WYDEN. I understand it, and I think your point is a good one. All we want to try to examine is that the prospect of having additional health care professionals involved. These health professional services must be less expensive than traditionally.

Ms. PETROSKI. I believe Title X is effective because primarily the care is rendered through nurse practitioners or allied health professionals.

Chairman WYDEN. Tell us what the waiting lists are like in Pennsylvania.

Ms. PETROSKI. I can address my particular facility. At this point in time we actually do not have a waiting list. As I indicated, that is because we are in a rather unique position in that we have a very large medical assistance population. So, they are in fact, receiving services. But we do get into a situation where we will have people on waiting lists that give them points in time. If we use up our 20 kits at the beginning of the year, we then have women on waiting lists.

I have indicated we have had women become pregnant while waiting for that subsidy to become available, which may technically be 9 or 10 months if we use them up at the beginning of the year.

Chairman WYDEN. Your program had women become pregnant while on the waiting list?

Ms. PETROSKI. Two, that I am aware of.

Chairman WYDEN. Ms. DeSarno, I think you heard me discuss this with Dr. Elders. You said the office wasn't fully operational.

Ms. DESARNO. All of the money wasn't appropriated to pay for it in the last year's appropriation.

Chairman WYDEN. That is something I can talk to Congress types, appropriators about.

Ms. DESARNO. Right.

Chairman WYDEN. You said also that pharmaceutical companies have no incentive to offer a public price for contraceptives.

Ms. DESARNO. These two, that they are sole-source drugs.

Chairman WYDEN. Your sense is that the Government providing small grants to alternative companies would be one of the best incentives, and next, to try to jar——

Ms. DESARNO. I think that is a way of making certain that in those incentives, there is language that says that they must offer a nominal price to publicly funded clinics.

Right now, in contracts that are given out, I would assume NIH or an entity of NIH could in fact, issue a request for proposal for a contract to develop a generic substitute for both Norplant and Depo, and as part of that contract language — I don't think it would require new Federal legislation — as part of that contract language, stipulate that for publicly funded entities a nominal price would have to be offered.

Chairman WYDEN. I think it is an excellent idea. You would envisage if a company were to pick up on something like that, possibly they could get expedited FDA approval and that sort of thing.

Ms. DESARNO. Yes, I do.

Chairman WYDEN. So if the Government was involved in trying to get a generic substitute out, it probably could get out pretty quickly.

Ms. DESARNO. Yes.

Chairman WYDEN. What can you tell us about the waiting lists?

Ms. DESARNO. They really vary. What we are really discovering right now is that our clinics are being overwhelmed by requests for Depo Provera. There are a couple of reasons for that.

One is that it is available in our clinics at about $33, counting the cost of the injection. For a poor woman who doesn't qualify to get it for free, you are more able to get together $33 over 3 months than to come up with $500 to get Norplant. It is also a 3-month method, and many women aren't ready to commit to a 5-year — if

you are a young woman beginning a marriage you may not wish to have a 5-year method. But we are overwhelmed right now with requests for Depo.

I think the other reason that waiting lists are dropping on Norplant and increasing on Depo is because women have learned they just can't get it. They have given up waiting, and the fear of pregnancy, when there is in fact, a method that they can get the money together for.

But both of these methods, if in fact, we made them available the way we would like to, we would use up all of our Title X funds probably in the first 2 months of operation.

Chairman WYDEN. Ms. Kaeser, let me ask you a couple of questions. One that is really ominous in your study, and I quote here, you said, "No Medicaid agency indicated it would cover removals among users who become ineligible." I gather what you are saying is once you solve the initial access to Norplant, women are still faced with financial access problems with respect to removal.

Ms. KAESER. That is absolutely right. I was pretty startled to find that. I suppose that is how Medicaid Programs work, i.e., that they cover only those who are eligible at the time, but I don't think they have ever had to deal with a method like Norplant before, where it lasts up to 5 years. People might in fact, want to have it out after 4 years in order to have a baby. There are all sorts of circumstances that we can't really predict for individual women.

But the issue of removals is very critical. As you saw from our study, removals can range between $100 to maybe $150. In addition, it is a question of finding a provider who will do it.

Providers haven't been adequately trained, or maybe the better way to say it is that they haven't had good enough continuing education. Quite a few providers who deal with Norplant now are quite good at insertions. But the fact is that now, as we have just passed the second year of its availability, removals are another question.

Chairman WYDEN. Removal is what, a couple of hundred dollars?

Ms. KAESER. I would say, in a publicly funded clinic, it is probably closer to $100. Most private physicians charge about $150. Just for the removal. That is not counting an office visit.

Chairman WYDEN. Is it fair to say if you have just gone off welfare, for example, and your financial circumstances have changed, it is a significant out-of-pocket——

Ms. KAESER. That is a significant cost, yes. I think it is wonderful that Ms. Decriscio did not have any side effects. Some women do. So, even with adequate counseling, which I also want to raise as being very critical to good Norplant use, many women just are not prepared for the side effects they experience, so they might in fact, want removals at an earlier time than 5 years.

Chairman WYDEN. What else can you tell us about the State's Medicaid payment policies? I think there was one State that would pay for early removal of Norplant when there was a medical reason.

Ms. KAESER. Only.

Chairman WYDEN. Which struck me as, the Government helps you get into the contraceptive program but not get out.

Ms. KAESER. I would say that is probably a result of the cost.

Chairman WYDEN. Just a cost issue for the State?

Ms. KAESER. I imagine.

Chairman WYDEN. Which State was that?

Ms. KAESER. This was Oklahoma. I did call back to verify that this was their policy, because I was fairly startled by it. But they did say that, yes, a woman may have it removed for medical reasons only.

I will tell you most side effects are not viewed as "medical reasons." Most side effects such as irregular bleeding and other things, are viewed as mere nuisance side effects. So, a woman has to truly be in danger of some medical problems before Oklahoma will pay for it to be removed before the end of 5 years.

Chairman WYDEN. Let me ask you one other thing that is striking about your study. It really looks like a hodgepodge, a kind of crazy quilt of pricing programs and eligibility requirements, both for insertion or removal. Do you find that this was hard for the clinics to sort out and make their way through?

Ms. KAESER. I am sure it is almost impossible. As Ms. Petroski said, where you have a high Medicaid eligible population that actually makes it easy. It is taking care of the people who are not Medicaid eligible. By the way, I think a lot of people forget that women who have never had a baby are unlikely to be eligible for Medicaid.

Mr. Combest mentioned earlier that younger women may not have a lot of responsible choices. Well, it seems to me that the good use of contraception is almost the ultimate in responsibility.

These are the women who actually can't get it. A lot of 18 year olds, who are just in their first job, it is very low paying and they are not covered by health insurance it is going to be very hard for them to get Norplant.

Chairman WYDEN. Well, all of you have been excellent in conveying your views, and forcefully so. As you heard earlier, discussions are already taking place in the Department of Health and Human Services with Wyeth in particular on Norplant.

Frankly, what our hearing has done is highlighted a whole host of areas that we need to focus on. We need to make this part of the debate for welfare reform and health care reform that is going to be addressed in this Congress. We need to look at ways to inject more competition into this field.

Government has clearly a role there. Ms. DeSarno has pointed out the Congress ought to be doing a better job in terms of trying to get funds for that office that is working on bulk purchasing.

So there is lots to be done here. But I can just assure you that this subcommittee thinks, dollar for dollar, the kind of health services you are talking about are as good an investment as our country can make. What these health services are all about is making sure that people can take control of their lives and have the options and the choices that they want regardless of their wealth.

I am not going to just sit idly by and let public health policy be created solely for the benefit of catering to an affluent market. We are going to turn this situation around. It is going to be easier to do it because good people like you have come and worked with us.

We will ask our minority counsel if he wants to ask any questions.

Mr. LEHMAN. Thank you, Mr. Chairman.

One question, Ms. DeSarno. You mentioned, and I am not sure when you mentioned this, but for oral contraceptives when they first came out, were they discounted — when they first came out you mentioned you could get a cycle for 65 cents.

Ms. DESARNO. Almost immediately. They go as low in our clinics as getting them for 4 cents a cycle. The Congress has given many ways for the drug companies to offer those prices, as Norplant and Depo could be offered, in a way that protects the company from still being able to market it at a much higher price to the general public, and almost from the beginning of the Title X Program, we have been receiving low-priced oral contraceptives.

Mr. LEHMAN. Would your suggestion for grants for generic substitutes, would you suggest that for cancer and AIDS and other things, or just in the contraceptive field?

Ms. DESARNO. I think it is an idea worth pursuing for a variety of drugs.

Mr. LEHMAN. Thank you.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank the counsel.

Let us say on both the minority side and the majority side, we will hold the record open for Members' comments.

[The information may be found in the appendix.]

Chairman WYDEN. You all have been excellent. We are going to be working closely with you in the days ahead. Do you have anything further you would like to add?

Ms. DESARNO. We would love to have full funding for Title X.

Chairman WYDEN. I will put on my hat on the Health Subcommittee.

Ms. DESARNO. You do it well.

Chairman WYDEN. I think you know Chairman Waxman is extremely sympathetic to that program. I will convey that as well.

The subcommittee is adjourned.

[Whereupon, at 11:55 a.m., the subcommittee was adjourned, subject to the call of the chair.]

APPENDIX

OPENING STATEMENT
REP. RON WYDEN

BEFORE THE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND TECHNOLOGY

IMPACT OF THE HIGH COST OF LONG-TERM CONTRACEPTIVE PRODUCTS ON FEDERALLY SPONSORED FAMILY PLANNING CLINICS, WELFARE REFORM EFFORTS AND WOMEN'S HEALTH INITIATIVES

March 18, 1994

For the last four years, the Subcommittee on Regulation, Business Opportunities and Technology has pursued an inquiry into the pricing of drugs and medical devices developed through research partially or entirely subsidized by federal taxpayers. Our primary concerns have been that (1) small drug and device manufacturers have equal access to these federally subsidized technologies, and (2) consumers who are paying for that subsidized research realize a return on their investment either in lower prices on federally supported medical breakthroughs, or in license fee revenues to the federal treasury.

During a November 10, 1993, hearing on the pricing of Norplant, a long-term contraceptive device commercialized, in part, through a $16 million taxpayer subsidy, the subcommittee reviewed a substantial differential between this product's U.S. and international price.

> In some overseas markets, this American product sells for less than 10 percent its U.S. price.

The manufacturers have posited a number of reasons for this differential. Today, the burdensome effects of that price, and the price of another long-term contraceptive, Depo-Provera, on family planning efforts will be described by the U.S. Surgeon General and health clinic administrators.

Our discussion is especially timely. The American people expect this Congress to enact welfare and healthcare reform...issues with bottomline implications for our small businesses. In the context of this debate, there has been considerable discussion about denying women on welfare, benefit increases when they have additional children.

At present, liberals and conservatives are fighting furiously over this politically and philosophically charged matter. Meanwhile, real answers are getting lost in the rhetorical fog. For example, giving women access to safe, affordable contraceptives to promote individual responsibility and ensure that they have the means to succeed.

Welfare families get bigger, in part, because birth control available to the mothers often fails.

Setting up financial disincentives to having more children won't do the job. Women need healthcare services that allow them to gain some control over their lives.

Virtually every public health professional testifying before this subcommittee has said that many women need long-term contraceptives...contraceptives which do not require daily decision-making and self-medication.

But as we shall hear, most clinics serving low-income women simply can't afford to stock these products. Client choice is diminished. Women have pregnancies they don't want. And the welfare rolls grow as more women drop out of school, and the workforce, in order to take care of unplanned families.

> Dollar-for-dollar, one of the most important investments this government can make is to ensure women can obtain contraception that meets their healthcare needs.

Currently, long-term contraceptives such as Norplant cost American women $700 or more, while they cost women in other countries $23. According to some estimates, the actual cost of manufacturing Norplant is $16. The exorbitant price of this product prohibits its use by uninsured, underinsured, and other lower-income women. For example, we heard recently that 80 percent of the women in central Pennsylvania who are served by family planning clinics do not earn much money but do not qualify for Medicaid, which pays for Norplant. This situation is particularly ironic, given the fact that American taxpayers paid for a significant proportion of its development.

Women who do not participate in Medicaid are 12 times less likely to receive long-term contraceptives such as Norplant. Availability is out of reach for two reasons: first, the initial cost is too high; second, the cost of removal may not be covered. Removal is a problem for users, whether or not they qualify for Medicaid. They are stuck! Access to long-term contraceptives should involve an affordable package of services, including the insertion and removal. The decision to start is a budget-breaker for most users. The freedom to stop is a financial ambush.

One of our witnesses, Lisa Kaeser from the Alan Guttmacher Institute, will speak to this problem. Guttmacher analysts have conducted an extensive, and very valuable survey of family planning clinics on the issue of high-cost products, and the financial balancing act clinic administrators must maintain in their attempt to provide the broadest possible choice to clients.

The Chair believes it is time for the Clinton Administration to mitigate the high cost of these contraceptives, especially for directors of federally supported family planning clinics. Today, we have with us the Surgeon General, Dr. Joycelyn Elders. She will describe the impact on family planning clinics across the country, and on the Administration's public health and welfare reform agendas.

She will also discuss actions that the government could take to lower the cost of long-term contraceptives.

It is the Chair's view...and we will appreciate Dr. Elder's thoughts on this...that there are really only three avenues of government intervention open at this time:

1. The government could become the bulk purchaser of long-term contraceptives for distribution in federally subsidized family planning clinics. The a steep discount could be achieved, with the savings passed on to the clinics.

2. The government could fund an accelerated research-and-development effort aimed at creating more products, and more competition, within the long-term contraceptive market place...again, with the expectation that price would decline and availability increase.

3. Finally, the Administration could use its bully pulpit, its political and moral suasion, to push for an immediate public sector price from the manufacturers of Norplant. The product's principal supplier, Wyeth-Ayerst, told our subcommittee in November that a discount price could be set two years from now. But we have good reason to look for a lower price much sooner, and the government should be pursuing that end.

At our November 10, hearing, in questioning Dr. Marc W. Deitch of Wyeth about the high price of Norplant, I was told, that, "If the product came to be seen simply as a product for public sector clients and lower-income users, we knew it would not be well accepted anywhere."

We know from Wyeth's expensive advertising campaign that the company is going to go to great lengths to market this device to affluent women. In recent years, I've heard a lot of novel theories to justify high pharmaceutical prices. But this elitist school of pharmaceutical pricing is morally repugnant.

Drug prices should be based on drug development costs, plus a reasonable profit, rather than some artificial standard that assures a market of upper income consumers.

Our other witnesses, today, include a consumer who will describe her experience in obtaining Norplant. And finally, representatives of family planning clinics will describe, from the ground-level view, how high contraceptive product prices handicap the day-to-day operations of these important healthcare agencies.

HONORABLE LARRY COMBEST

HOUSE SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES AND TECHNOLOGY
March 18, 1994

Mr. Chairman, this morning we will delve back into the issue of drug pricing for long-term contraceptive products. At the subcommittee's previous hearing in November we heard from a series of witnesses that surprisingly agreed on a majority of issues.

Participants agreed that not enough public or private research is being undertaken to develop contraceptive products. Secondly, the Norplant system is considered a breakthrough product in contraceptive technology. Finally witnesses agreed that although the five-year cost of the product is similar to other alternatives on the market, the up-front cost has caused access difficulties for poor women.

I believe that cooperative efforts between Wyeth Labs and the federal government should be further encouraged in an effort to establish a financing mechanism or other alternatives to increase the availability of this product. I am fearful that the high decibel rhetoric by some who would have the federal government mandate prices onto private business would have devastating consequences. Not only could it lead to intransigence by corporate leaders, but in the end it would not result in any increased availability of the product to those who need it.

I believe it is fundamentally incorrect to berate the lack of research and development of these socially sensitive products in the private sector and then advocate strict government price controls. I have no faith in government bureaucrats knowing what the "right" price is for a pharmaceutical product or any other product. Once we set the dangerous precedent of government price controls, it will result in shortages and inefficiencies in the marketplace.

Lastly, I would like to comment on the deafening silence from health care leaders as it relates to personal responsibility and abstinence. It appears that the fundamental shift away from teaching core values and abstinence and instead focussing on contraception and abortion has completely failed our youth. In the last 30 years, illegitimate births have increased more than 400 percent. In 1990, almost 2 million abortions were performed.

While teens are being bombarded with pro-sex messages from Hollywood, musicians and from their peers, government health officials have spent little time or money advocating abstinence. I understand there are new successful abstinence programs in California and Maryland. It is certainly time for health care leaders to offer our childeren a different, healthier message.

Chairman Wyden, Mr. Combest and members of the Subcommittee, I am pleased to be with you today to talk about the impact of the high pricing of long-acting contraceptives such as Norplant and Depo Provera on access for American women.

While long-acting contraceptives have the potential for significantly expanding the contraceptive options available to American women, high prices remain a major barrier to access. Norplant and Depo Provera represent significant breakthroughs in the last thirty years in the contraceptive technology available in this country. I feel that they are priced out of reach for too many women. If reproductive choice is to be a reality in our country, reproductive choice must include access to the latest, most effective means of contraception.

At the outset, I want to express my personal appreciation to the Upjohn company for persevering in its efforts to have Depo Provera approved for contraceptive use. I also want to express appreciation for Wyeth's efforts on several fronts, including: introducing Norplant to this country; its efforts in training health professionals in implant

insertions and removals; its ongoing research activities focused on women's health; its plans to provide a public sector price at the end of the initial five year period, and its efforts to make the method more available to poor women through the Norplant Foundation, which I understand, has served 13,000 women thus far. However, I also want to make it clear that the fundamental problem remains -- the price of Norplant and of Depo Provera is too high in this country for a large portion of working poor women to realize "contraceptive equality."

As you know, I am committed to reducing the high rates of adolescent pregnancy and unintended pregnancy in the country by ensuring that all women have access to the widest possible range of contraceptive choices. That is where I concentrated my efforts as Director of the Arkansas Department of Health and it is where I plan to continue concentrating my efforts as Surgeon General. While in Arkansas, I was a strong advocate for making Norplant available as an additional effective option for women. I supported Norplant training. I also worked especially hard to ensure that poor women who wanted it, and were eligible for Medicaid covered family planning services, received

Information about and access to Norplant during the sixty day post-partum period of Medicaid coverage.

You have heard me repeat many times, "Every child in America should be a planned, wanted child." With 57 percent of all births in the country considered unplanned or unwanted, we need to ensure that the newest, most highly effective methods of contraception are not priced beyond the reach of a majority of American women. Norplant offers a very effective method to help women who want to plan and space their pregnancies because of its great advantages in:

(1) providing continuous and long-acting contraceptive effectiveness,

(2) not requiring daily maintenance,

(3) being fully reversible, and

(4) its use does not disrupt the sexual encounter.

Consisting of six implantable hormonal capsules, Norplant is inserted just beneath the skin on the inside of a woman's upper arm. Norplant provides contraceptive protection over a five year period through the gradual release of the contraceptive agent, Levonorgestrel. Both insertion and removal of the implant entails a minor surgical procedure that can be performed by physicians, nurse practitioners, certified nurse midwives and physicians' assistants, depending on the provisions of a State's clinical practice laws.

Manufactured in Finland for world-wide sales, Norplant is distributed in the United States by Wyeth-Ayerst, which owned the patent for the active agent, Levongestrel, and is licensed for exclusive distribution of the product under an agreement with the Population Council (the organization which originally developed Norplant). In the three years since the implant first became available for use in the United States, almost one million kits have been marketed in this country.

Depo Provera is an injectable contraceptive with an effectiveness period of three months per injection. Depo Provera was approved by

the FDA as a cancer palliative in 1960 but was not approved for marketing as a contraceptive until 1992. Depo Provera relies on a single injection every three months, after which the concentration of the effective compound gradually dissipates. Dosage appears ample, and in some studies, reinjection on a six month schedule has been tried. Because the drug remains in the body longer than 3 months, it has an extended effect on ovulation and return to fertility may be delayed several months after discontinuing use of Depo Provera. One unique benefit of Depo Provera is the degree of privacy it affords the user. With no daily or coitus-related contraceptive to use or carry, and no palpable or visible rod outlines as with Norplant, Depo Provera allows a woman to be protected from unwanted pregnancy with complete privacy.

When first made available in the United States in early 1991, Wyeth set a universal price of $350 (subsequently raised to $365) for the Norplant kit. However, when insertion and overhead costs are added, the overall charge for a Norplant implant can exceed $700 -- pricing it well out of the reach of many women. At the same time, Norplant is

sold internationally to governments and nonprofit agencies in less developed countries for as low as $18 (with an average price of about $23). Why the huge difference in pricing overseas? While the Norplant product marketed in developing countries includes only the six capsules and trocar, in the United States the product is packaged in a kit with surgical equipment and counseling materials. Wyeth also provides extensive training to clinicians for patient counseling and insertion and removal of the rods. However, neither the additional materials in the kit nor the additional training seem to justify the high cost of Norplant in the United States.

Depo Provera is manufactured by the Upjohn Company, and is priced for contraceptive purposes at about $30 per injection or $120 per year, not including the provider's fee for each office visit. Upjohn has long been providing Depo Provera for non-contraceptive uses for about $12 per dose. It is odd that, when this drug is approved for contraceptive use which greatly expands the market for this compound, the price moves up instead of down, as one might expect under economic theory.

Access to Norplant is far from universal. The high price of Norplant in this country and the failure of Wyeth to offer Norplant at a lower public sector price has created a serious dilemma for family planning providers. While the prices of Norplant and Depo Provera are less than the total retail price of a 5 year course of oral contraceptives, the fact is that most other contraceptives are made available to clinics at a substantially reduced public sector price. We also must bear in mind that the average duration of the use of a Norplant device is less than its five-year effective life. In comparison to these prices for a five year supply of oral contraceptives, condoms, and other methods, the cost of Norplant and Depo Provera to clinics, and therefore, to their poor and moderate income women, is exorbitant. Women on each end of the income scale -- those eligible for Medicaid and the affluent -- can get these products, but there is a huge gap in availability for those women in the lower/middle income brackets, those we often call the working poor.

Public funding to assist low and moderate income women in obtaining contraception comes from several sources -- Medicaid, the Title X

family planning program, other Federal health programs and State family planning programs. A recent survey by the Alan Guttmacher Institute indicates that Medicaid is the largest single source of public funding for Norplant insertions, paying almost 90 percent of all the publicly funded insertions in 1992. We know that a large portion of these insertions occurred during the sixty day, post partum period. As a State Health Director, I pushed to get women Norplant during this period of coverage. It is unfortunate that our clients had to first have a baby before they were provided access to this new contraceptive method.

Depo Provera and particularly Norplant are virtually inaccessible for women whose incomes exceed the Medicaid threshold and who don't qualify for AFDC. These women are often not covered for the implant by private insurance plans; they are the "working poor," the many women who are uninsured and underinsured. These women too often lack a clear voice of advocacy here in Washington because they are so involved with the day-to-day grind of raising their children, making ends meet, and trying to stay off welfare. Depo Provera and Norplant

are also unavailable to adolescents, a group for whom easy access to reproductive health care is always a problem.

The high price of Norplant and Depo Provera thwart the ability of public health providers, especially family planning clinics, to provide reproductive equality to all clients. Once their allotment of these products has expired, most clinics cannot afford to purchase additional supplies. Although Title X clinics, for example, are required to offer all contraceptive methods, they are not required to offer any specific quantity of a particular method if this action is considered budgetarily unsound. Norplant and Depo Provera are provided on a first-come, first-serve basis until the supply is exhausted -- which often happens quickly, as demonstrated by long waiting lists. The combination of limited program funding and the high cost of Norplant and Depo Provera presents clinics with the dilemma that, for every woman provided a Norplant implant or placed on a Depo Provera regimen, several others may be denied less expensive contraceptive methods -- in effect limiting the overall options of all clients and certainly reducing the number of clients served by the program.

When this denial or limitation results in a low birth weight, unwanted child, we all pay for this inequity.

Although Federal legislation mandates that drug manufacturers offer federally funded health care providers a price discount of 15.7 percent off their available best price, this is not nearly enough. All 50 States and the District of Columbia include Norplant and Depo Provera in their Medicaid formularies at retail price minus the mandated discount. This only reduces the price for Norplant to approximately $300 per implant and the price of Depo Provera to about $23 -- still excessively expensive for public providers and out of reach for women who are not Medicaid eligible.

In an attempt to make Norplant more readily available to low-income women who would not have access to the product (for instance, they may not be Medicaid eligible), Wyeth established the Norplant Foundation which makes kits available to providers serving low-income women. However, to date only 13,000 kits have been distributed which probably reflects the limitations placed by the

Foundation on the number of free Norplant kits a provider may receive, as well as the other barriers the foundation imposes including the fact that clinicians may not charge for the costs associated with insertion and removal. When considering the over-all demand for Norplant, the free kits distributed annually through the foundation for poor women is negligible compared to the approximately one million kits that were distributed in this country since it was made available in February, 1991.

I am pleased that Wyeth has announced that they will reduce the public sector price for Norplant after the first five years of distribution. However, we cannot wait that long. Most likely, the new two-year, two-capsule Norplant system soon to be released by Wyeth and the Population Council will make Norplant somewhat obsolete. Although a release date and potential price have not been made public, I would urge Wyeth to provide special pricing for non-profit or public sector providers when the product is released. I would also urge Wyeth to strongly consider offering Norplant capsules to the public sector at a

reduced, affordable price without all the fancy packaging and accompanying brochures.

In summary, Norplant and Depo Provera are significant additions to the array of contraceptives offered in this country. After many years without new innovative contraceptive products, it is exciting that these two, highly effective methods of contraception have made their way into the market place. As committed public health professionals, our goal is to provide access for every women in America to the contraceptive method of her choice at a reasonable and affordable price. Yet, we are at a frustrating impasse because the fundamental obstacle to making long-term, highly effective contraceptives universally available still remains -- too many women in this country have no freedom of choice because they are denied access due to high prices. I appreciate your assistance in drawing attention to this issue and the efforts you are making to ensure that this problem is addressed in the very near future so that all women can enjoy contraceptive equality. Thank you. I will be happy to answer any questions you might have at this time.

TESTIMONY PRESENTED BY

CATLEEN DECRISCIO, NORPLANT RECIPIENT
FAMILY PLANNING CENTER OF ALTOONA HOSPITAL

before the

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY

THE HONORABLE RON WYDEN, CHAIRMAN

MARCH 18, 1994

TESTIMONY OF CATLEEN DECRISCIO

Mr. Chairman, members of this Subcommittee, my name is Catleen DeCriscio and I am a 27 year old mother of two children. I live in Altoona, Pennsylvania, and am the recipient of a grant which enabled me to receive Norplant in December 1993. I am very pleased with Norplant and would recommend it to many people, if, of course, they could afford it.

I learned about Norplant at the Family Planning Center of Altoona Hospital when my nurse practitioner at the center showed me a pamphlet on birth control options. I don't have health insurance or any other way to pay for expensive birth control. At first, Norplant did not look like an option for me because I work part-time and my husband and I don't have health insurance. We also don't qualify for Medicaid because, between the two of us, our income is considered too high. There is no way that my husband and I could afford the $515 for Norplant without insurance coverage or a grant; $515 is more than both our house and car payment. My nurse practitioner told me that if I really did want Norplant, it might be possible for me to receive Norplant through a grant, although the chances for this, I was told, were slim. There are several sources for Norplant grants. I received a Norplant kit from the Norplant Foundation; however, the insertion fee was not covered by the Foundation. The Family Health Council of Pennsylvania donated money for the insertion procedure. We filled out forms in October and in mid-December, I was finally granted Norplant insertion free of charge. I am so pleased to have Norplant, I can feel protected for five years, and I can have Norplant removed at any time if I wish. I have felt no adverse side effects and I feel empowered by the ability to decide

when and whether I want to have another child. Norplant has made such a difference for me; I definitely prefer it over other birth control methods. Previously, I used condoms and the pill, but I wanted a more long-term contraceptive with fewer side effects. The pill gave me headaches, mood swings, and it was hard for me to remember to take them every day. My family also has a history of breast cancer and this made me feel uncomfortable about taking the pill. If I didn't have Norplant now, I would have continued with the pill even though I wasn't comfortable with the side effects and potential health risks of it.

I was one of the lucky women who actually did receive a grant for Norplant. Norplant is such a great birth control option for women, it is a shame that it is not available to us all. I recommend Norplant to many of my friends, but few can pay to have it inserted. For a woman such as myself and for many others like me who work part-time, raise children, and are <u>not</u> interested in more children for the time being, Norplant is an ideal contraceptive; the problem is that we can't afford it! I am appalled at Dr. Deitch of Wyeth-Ayerst who justifies the high price of Norplant by saying that it will not be seen merely as a poor woman's method of birth control. Birth control, of all things, should be available to all women, regardless of their income level. People like myself are left out of the system because we are caught between the benefits packages of two classes and we don't fit into either. I was lucky to receive a grant, but don't let the existence of the Norplant Foundation fool you into thinking Norplant reaches many middle and low income women; my situation is unique and not many women are as fortunate as I am.

In closing, Congressman Wyden, I appreciate all of your work and the work of

the Committee. I strongly urge Wyeth-Ayerst to reconsider and reduce the price of Norplant. It is an outstanding contraceptive and economics should not bar women from utilizing it. Thank you.

Good morning, Chairman Wyden and members of the Subcommittee. My name is Marian Petroski and I am the Executive Director of the Altoona Hospital Family Planning Center in Altoona, Pennsylvania. I am delighted to have this opportunity to testify before you this morning regarding my clinic's experience with Norplant.

At the Family Planning Center, we serve over 4,000 women annually. We provide comprehensive reproductive health care to anyone who enters our clinic, regardless of income. This mission has become harder and harder to fulfill in recent years. My clinic is located in Altoona, a small industrial city in central Pennsylvania. Our center is the only family planning provider in Blair County, a largely rural area about two hours from Pittsburgh. Our area was hard hit by the industrial declines of the 1980s, and we continue to have unemployment rates that far exceed the national average. In Altoona itself, and in the surrounding rural Blair County, the numbers of uninsured and underinsured have continued to grow, many of whom have come to our clinic to fill in the gaps in health services.

We have made Norplant available to our patients since 1992. To date, we have inserted approximately 200 implants. Out of those 200, only 2 -- 1 percent -- have been paid for by our full pay patients. Of the remaining 198, almost all have been paid for by Medicaid, even though only 28 percent of our patients are eligible for Medicaid. A very few lucky women-- about thirty -- have been able to obtain Norplant free of charge. Twenty of these women were able to get Norplant kits for free via the Norplant Foundation, which made them available to the two doctors at my clinic. Initially, we were told by Wyeth that each physician had a lifetime limit of ten free kits -- which we quickly ran through. I now

this has been changed to an annual limit of 10 kits. While this revision is an improvement, it still falls short of supplying adequate numbers of kits, in part because the Foundation will only supply them to physicians affiliated with the clinic, rather than to the nurse practitioners who provide the bulk of care at most family planning clinics. In addition, there are numerous administrative hoops that both the physicians and the would-be patients must jump through before the Norplant Foundation is willing to make kits available. Therefore, it is not surprising that, of the 200 Norplant kits we have inserted, only about ten percent were donated by the Norplant Foundation. In addition to the 20 donated kits, we have been able to obtain ten kits made available by a special subsidy from the Family Health Council of Central Pennsylvania, the Title X grantee for my area.

Even when the Norplant Foundation donates kits, there are still many attendant expenses. It is only the kit itself that is free. Thus, even for so-called "free" kits donated by the Norplant Foundation, (for which Medicaid pays a little over $300), we absorb over $200 in costs associated with a full cost a GYN examination, counseling, the insertion itself, a follow-up visit, and removal. So you can understand why, given our extremely tight operating budget, it is impossible for us to absorb the entire $500 cost for individuals who cannot get either a kit donated by the Norplant Foundation or who are not eligible for Medicaid and still continue to offer reproductive health services to our other clients. There is just no amount of judicious budgeting that can make up for that kind of money.

Mr. Wyden, as I have indicated, it is virtually impossible for a poor woman to get Norplant at

my clinic if she is not eligible for Medicaid Assistance, despite the fact that Medicaid covers only one segment of the poor women who could conceivably benefit from this product. For women below 100 percent of the poverty level who are not eligible for Medicaid because they are trying to avoid their first pregnancy, very limited resources are available. There is an additional group of poor women with incomes above 100 percent of the poverty level, the absolute cutoff for eligibility for the few available free Norplant kits, who still cannot afford the $500 price tag. Thus, many women who are poor, but not sufficiently poor, are being denied access to their optimal birth control method.

While the demand for Norplant has leveled off somewhat, in part because of new interest in Depo-Provera, we are still in the uncomfortable position of forcing many women to elect their second choice method. Because of Norplant's high cost, some women leave our clinic with no method of birth control but return down the road for either Norplant or a different method. Other women, however, just fall through the cracks -- some are transients, some seek help elsewhere and some become pregnant. I can tell you that I know of at least two women at my clinic who became pregnant while waiting for Norplant to become available. We just can't afford to miss these opportunities to provide needed contraceptive services, not to mention essential primary and preventive care.

Our inability to provide Norplant to all comers is a problem especially for the young women we see, who are in many instances ideal candidates for Norplant. For sexually active teenagers who are seeking to postpone childbearing for financial reasons, to attend school, or

to obtain other career training, we do a real disservice to them by effectively limiting their contraceptive options. We also know that if women are unable to obtain the contraceptive method that is their first choice, they are less likely to use it consistently and correctly. And waiting until women can save $515 to pay the up-front cost of Norplant puts many at risk for unintended pregnancies. We can't afford to lose these women when they seek to make responsible choices. Nor can we afford to turn away poor women who have no other source for confidential reproductive health services. I cannot emphasize enough the importance of confidentiality -- something which is guaranteed by all Title X clinics.

The high cost of Norplant also puts clinic staff in the untenable position of offering nondirective counseling to women about all contraceptive options, when in reality they are not equally available because of cost. The Title X guidelines are very clear that all options must be presented to clients. However, the program does not provide the level of funding that would enable us to provide all services to all clients. If a non-Medicaid eligible woman requests Norplant and funding is not available, our policy is to place her on a waiting list or refer her to another clinic where the device may theoretically be available. However, this course of action is a bit disingenuous in light of the true availability of Norplant. Mr. Chairman, the reality is that we cannot offer women real alternatives---the closest referral site is over an hour away and I know for a fact that this clinic is in no better position to offer Norplant to poor women than we are. The truth is that the women we serve do not understand why this product costs so much and, because we share their confusion, we too can't offer them a satisfactory explanation. To our clients, $500 pays the month's rent and

grocery bills. Clearly, there is no adequate justification for forcing women to choose between the necessities -- birth control on the one hand and food and a roof over one's head on the other. Mr. Chairman, you and I know that this is a choice no woman should ever have to make.

However, I keep returning to the bottom line because this is what ultimately counts. Because the state Medicaid program pays $500 for a Norplant insertion, we are able to provide this service -- thus creating a two-tiered system. Clearly this is not the message we want to be sending. However, at the same time, my clinics cannot absorb the tremendous expense of Norplant for non-Medicaid patients who are too poor to pay the entire cost of the product. For some women, the introduction of Depo-Provera has been an answer to the high up-front cost of Norplant. While the cost of Depo -- $33 every three months -- can be significant to a woman who is struggling to get by -- it is far easier to come by than $515 for Norplant. Depo also necessitates more frequent clinic visits -- which in some cases is a problem for women living in the rural area we serve who often lack regular and reliable transportation.

The only way I can see to remedy the current situation is not to earmark special funds as the State of Pennsylvania has considered doing, making a precious few kits available for free via the Norplant Foundation and pretend that this translates into access for poor women, or to have women using a method that they deem less than optimal. Instead, it is imperative to make Norplant (and Depo-Provera as well) available to public clinics such as the Family Planning Center at a greatly reduced price so that we can give our patients what they really

want -- immediate access to safe, affordable, and long-lasting contraceptives. The kits provided by the Norplant Foundation are a drop in the bucket given our need and there is no significant discount at all available for Depo-Provera. The Title X, Title XX and Title V dollars that we have available for family planning services are always in short supply and have not kept pace with the increasing cost of contraceptive drugs and devices. In 1993 alone, our overall cost of pharmaceuticals escalated by over 20 percent -- in part fueled by the high cost of Norplant.

Mr. Wyden, as a clinic director, I know that we cannot afford to let our patients fall through the cracks. I also know that as a country, we cannot afford to have women's choices artificially constrained by pricing policies which allow pharmaceutical companies to reap tremendous profits at the expense of poor women. I urge you to take whatever action is necessary to ensure that Norplant be available at public clinics at a greatly reduced price. Thank you.

TESTIMONY PRESENTED BY JUDITH M. DESARNO, PRESIDENT & CEO
NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION (NFPRHA)
Presented to
HOUSE SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY
HOUSE COMMITTEE ON SMALL BUSINESS
March 18, 1994

Mr. Chairman, members of this Subcommittee, my name is Judith DeSarno. As President of the National Family Planning and Reproductive Health Association (NFPRHA), it is an honor to appear before you this morning.

NFPRHA is a nonprofit membership organization established in 1970 to improve and expand the delivery of voluntary family planning and reproductive health care throughout the United States. NFPRHA represents the entire family planning community, including state and local health departments, hospital-based and freestanding clinics, Planned Parenthood clinics, and family planning councils. Virtually all of the grantees funded under Title X of the Public Health Service Act are members of NFPRHA and together they provide services to over four million low income women, men, and adolescents at more than four thousand clinics nationwide.

I appreciate the opportunity to, again, address this Subcommittee. When I appeared before you last November, I outlined in detail the efforts that NFPRHA has made to obtain a deeply discounted price for Norplant for the Title X clinic system. I explained that the clinics receive oral contraceptives at an average price of 65 cents

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and that the cost of the Norplant device remains a very high $300 for the PHS-funded clinics. I described the steps we have taken to try and work with Wyeth-Ayerst to obtain Norplant at a deeply discounted or nominal price, standing practice with their birth control pills. All to no avail. We have the same problem with Depo-Provera, although the Upjohn Company has indicated in recent weeks that they are willing to open discussions with NFPRHA about the possibility of a lower price for Depo.

In the meantime, the situation leaves our clinic staff completely exasperated, wreaks havoc on our clinics' financial viability, and effectively discriminates against our patients. You will hear first-hand from those in a position to articulate these views in a few minutes. I would like to focus my testimony on the over-arching public policy which governs today's discussion.

Mr. Chairman, Title X clinics are required to offer all contraceptive options to our clients, and our clinicians are extremely conscientious about taking the time with each woman to determine which option best suits her needs. Most of our clients are familiar with and request oral contraceptives (OCs) which we provide free for women at 100% of poverty, and for a very modest fee for women between 100% and 250% of poverty. Again, the average cost of a cycle of oral contraceptives to our clinics is 65 cents -- well below even the definition of nominally-priced drugs.

A completely different situation faces Title X clinics with respect to the two newest

contraceptives -- Norplant and Depo-Provera -- and in many cases they represent a superior method for our clients. In addition to requesting Norplant, which costs our clinics $300 per kit, our clients are increasingly requesting Depo-Provera, which costs our clinics $21.95 for a three-month injection. Our clinics, however, can only respond to a fixed number of requests for Norplant or Depo because there is no public price for either method. The cost of purchasing these contraceptive methods alone -- without factoring in the cost of providing the implants or injections -- means that it is virtually impossible to respond to the demand for these options without dramatically decreasing the number of clients we currently serve. Scaling back the number of women served -- when there are already so many not receiving our services -- is simply unconscionable. In short, Mr. Chairman, Title X clinics -- grossly underfunded to begin with -- are being forced to deny a woman her first choice of contraceptive, place her on a waiting list, again try to juggle an already stretched budget, and lament our inability to afford to offer Norplant or Depo-Provera to each of our clients.

In our discussions, Mr. Chairman, we have explored possible solutions to this dilemma. Current law permits the federal government to negotiate bulk purchases on behalf of public health entities. However, the office at HHS in charge of this authority is not fully operational. And, even if it were, the true obstacle in negotiating a nominal price for either contraceptive method is competition. Each of these is a sole source product. There simply is no incentive for either pharmaceutical

Subcommittee's last hearing on contraceptive drug pricing, the manufacturer of Norplant stated that one of the reasons that the price of this product was set -- and remains -- so high is to ensure that it will not be seen merely as a poor woman's contraceptive option. Dr. Marc Deitch, a Wyeth-Ayerst Vice President, stated that if the product came to be seen simply as a product for public sector clients and lower-income users, that the company knew it would not be well accepted anywhere. My reaction to this statement is, quite frankly, utter contempt.

Far from distancing itself from reaping profits on the use of Norplant by poor women, Wyeth-Ayerst actively sought Medicaid approval in all 50 states. Further, Wyeth-Ayerst supports state legislatures throughout the country earmarking funds for the purchase of Norplant kits. And, I can assure you, Mr. Chairman, that the states are not getting any special deal. They are paying $300 per kit just like the rest of the publicly supported health centers. So, on the one hand, the company doesn't want to associate itself with low-income users because to do so might undermine its marketing plan; and on the other hand, the company is promoting its product to every state health director in the country.

This is a true dilemma for us. NFPRHA obviously wants every poor woman to have the choice of this contraceptive available to her. However, for this company to refuse to offer a deeply discounted public price -- using the marketing excuse that they do not want it seen as a poor woman's contraceptive -- only to turn around and lobby

company to offer a public price. Any real solution, however, seems very far away right now.

One solution which may be worth exploring is providing grants to small pharmaceutical manufacturers to develop contraceptive drugs or devices. As part of the contract for receiving federal assistance in financing the research and development, manufacturers would have to make public prices available. Congress could also pass legislation to require a similar arrangement if the R&D is partially financed by public funds, such as in the case of Norplant. The Contraceptive Development Branch at the National Institute of Child Health and Human Development (NICHD) might be the appropriate governmental agency should Congress decide to conduct the R&D itself. I note that both Norplant and Depo have gone off patent and, perhaps, the first place to begin is by giving a grant to companies willing to produce a generic substitute.

Given current budget constraints, I don't anticipate that Congress will be able to provide Title X clinics with sufficient monies to purchase adequate numbers of Norplant kits or Depo-Provera injections without a publicly discounted prices. And to be perfectly candid, Mr. Chairman, any additional funds received by Title X clinics should really be used to expand our services, restore our outreach and education programs, and reach those individuals who are in need of our services but who are not currently receiving care. I find it very distressing that, during your

state legislatures to purchase the drug at full price -- is disgraceful. They are making a small fortune on serving poor women through Medicaid and through state-funded earmarked programs. States should refuse to earmark funds for a particular contraceptive unless that company is offering a deeply discounted price. Further, those states wishing to earmark precious health care dollars for family planning should leave it to the clinics to decide with their patients which is the best contraceptive choice.

I hope that I have made some suggestions which may be helpful to the Subcommittee in its quest for a solution to reducing the cost of new contraceptive methods for all women in this country. I commend you and your staff for your commitment to searching for ways to assure that the full range of reproductive health care is available without regard to one's ability to pay. I look forward to working with you in the coming months, and I hope you will call upon NFPRHA if we can be of any assistance. Again, thank you for extending me an invitation to testify this morning. I will be happy to respond to your questions.

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Testimony of

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Subcommittee on Regulation, Business Opportunities, and Technology

Hearing

March 18, 1994

The Alan Guttmacher Institute (AGI), a not-for-profit corporation for reproductive health research, policy analysis and public education, appreciates the opportunity to share with the committee the results of three recently completed studies by AGI that may shed light on the provision of contraception in the United States, specifically the contraceptive implant, sold in the U.S. under the trade name of Norplant. These studies were supported in part by The Henry J. Kaiser Family Foundation and conducted in 1992 and 1993. With your permission, Mr. Chairman, we would like to submit them for the record.

As you know Norplant shares several traits with other long-acting contraceptive methods that make it appealing to a wide range of potential users: It provides continuous contraceptive protection for up to five years with no action required of the user after it is in place, and its contraceptive action is fully reversible. Yet the high up-front cost of the device itself and of the minor surgery which is required for its insertion and removal has put Norplant out of reach of many women who might want to use it. (However, if the cost of Norplant is amortized over five years, it is comparable to other reversible methods.)

To begin, I would like to summarize some of the major findings from the two AGI studies related specifically to Norplant mentioned above, and a third, even more recent one, on private insurance coverage of reproductive health care services. Taken together, this research provides the best picture to date of the public and private sector coverage of Norplant in the United States.

As you recall, Norplant first became available on the U.S. market in February 1991, the first major new method in years. However, it took many states a period of time before they were able to make the method available using public sector funds. The first survey, conducted by AGI Senior Public Policy Associate Lisa Kaeser, assessed levels of public funding spent on Norplant in 1992, and reviewed the development of policies under which those funds were made available. Since each agency plays a different role in the provision of family planning services, we surveyed all of the state Medicaid, health

and welfare agencies, plus the 12 area offices of the Indian Health Service. It should be stressed that the data we present measure provision in the public sector only, and for several reasons, may somewhat underestimate expenditures.

In 1992, nearly 10% of the $645 million in public funds allocated for reversible contraceptive services in the U.S. -- approximately $61 million were spent to provide the implant to low- and moderate-income women. That year, public funds paid for over 150,000 insertions, and nearly 6,500 removals. Most of this was federal funding. Only nine states committed monies from their own coffers, about 7% of the total, or $4.6 million. Medicaid was the single largest source of public funding -- 94% of all federal funds spent on Norplant and 84% of all public funds spent by statewide agencies were provided by Medicaid. Although the Title X program is the only federal program devoted solely to funding family planning, the $1.8 million in Title X funds spent in 1992 by state agencies represents a mere 3% of the total public funds spent on Norplant.

We also looked at state administrative policies that might encourage use or limit the availability of this new method. Forty-one state health departments stated that they make available Norplant in at least some of the clinics they support, and of these, 27 have a policy requiring that clinics funded with state monies must make the implant available to all clients who are eligible for the clinics' other contraceptive services. Thirteen state Medicaid agencies reported policies that limit the number of Norplant insertions they will pay for in any time period; eight of these limit coverage to once every five years. Further, no Medicaid agency indicated that it would cover removals among implant users who become ineligible for Medicaid while the implant is still in place if they need to have it removed for medical reasons or because they want to become pregnant -- a situation in which women who are eligible during the postpartum period as a result of the recent Medicaid maternity care expansions may readily find themselves.

One Medicaid agency -- in Oklahoma -- reported a policy that restricts coverage of removals prior

to the end of the five-year lifespan of the device to "medical reasons" only; if a Medicaid-eligible woman chooses to have the implant removed for any other reason, she must pay for the removal herself. In contrast to Medicaid agencies, eight health departments responded that they did have policies ensuring subsidized removals for women who become ineligible for Medicaid before their implants expire.

None of the agencies reported that, for insertion, women must meet any age or marital status criteria, or criteria regarding the number of children they have, nor did they report any monetary incentives to women to promote acceptance or retention of the implant at the agency level. However, two states require a parental consent requirement before adolescents may obtain Norplant -- Utah and South Carolina. Utah has a state law requiring parental consent for all contraceptives provided to minors; South Carolina's is based on an attorney general's ruling that since Norplant involves "surgery," parental consent is necessary. While Utah state and local health departments have been ineligible for Title X funds since its consent law's inception in 1981, South Carolina's public agencies continue to receive Title X funding. Nor are the teens in these two states the only ones who face this type of restriction. Our second study of family planning clinic providers, which I will now turn to, found that fully a quarter of these providers enforce a parental consent requirement for Norplant, but are under no state-level mandate to do so. Because of its long-term effectiveness, providers routinely encourage adolescents interested in the method to discuss it with their parents. However, a teenager who is reluctant to talk about contraception with her parents may find that implants are off-limits for her.

This study looked at the ability of family planning providers, as distinct from the state agencies that set overall policies and provide financial subsidy, to make Norplant available to their clients, as well as the practices and policies adopted by these providers to deal with the unique aspects of the implant. In this study, conducted by AGI Senior Research Associate Jennifer Frost, a sample of over six hundred publicly funded family planning providers were surveyed, including hospitals, health department clinics, Planned Parenthood affiliates and others.

By September 1992 – nearly two years after Norplant came onto the U.S. market, only 40% of family planning providers were offering the implant to their clients. Hospital-based clinics and Planned Parenthood affiliates moved most quickly to initiate implant services. Only 30% of health department clinics were offering Norplant by this time. Among the providers that had not yet begun to offer implants, the lack of trained clinicians and cost considerations were cited as the paramount reasons: 60% stated that their staff had not been trained to insert or remove implants, 39% reported that the clinic itself could not afford implants, and 22% claimed that their clients could not afford implants.

If a woman attending a family planning clinic is not a Medicaid recipient or does not have private insurance that will cover both the device and its insertion, she may face a variety of pricing policies that vary widely from clinic to clinic. Over half (53%) of all family planning providers report that some low-income women who are not covered by Medicaid or private insurance may be eligible to receive implants for a reduced fee using a sliding scale based on their income, while 33% of the providers surveyed reported that fixed fees are charged to all women desiring implants who do not have other coverage. Pricing policies were found to vary by provider type with hospitals being the least likely and health department clinics being the most likely to offer contraceptive implants for sliding fees. The median fees charged for insertion by providers who use a sliding scale range from $2 to $485, and the median fee charged by providers with fixed fees is $500. The corresponding typical charge to have implants removed ranges between $0 and $111 for providers with sliding fee scales, and is $100 for providers with fixed fees. It should be noted that the fact that providers report a sliding fee policy for implant services does not necessarily mean that many low-income women will actually receive Norplant for a reduced charge. Unless the woman is a Medicaid recipient, the chance that she will be able to find a clinic that is able to use other public funds to pay for implant insertion is relatively small. Fully 63% of all implants provided at family planning clinics were paid for through the Medicaid program. Other public funds paid for 22% of all implant insertions at these clinics; however, 42% of all providers report that

all of their implant insertions had been paid for using exclusively Medicaid public funds.

The results of these two studies demonstrate the primacy of the Medicaid program in providing access to Norplant among poor women, even while that access remains uneven. A woman on Medicaid attending a family planning clinic is 12 times more likely to be provided Norplant than is a non-Medicaid eligible woman attending the same family planning clinic. Still, the ability to choose Norplant is not completely assured even to Medicaid recipients, since removals are not covered by any state Medicaid agency if a woman becomes ineligible during the life of the method. Further, although Oklahoma's "medically necessary" removal policy is not life-threatening, it severely limits a woman's ability to choose to become pregnant or, in the event that side effects become unbearable, to choose another method.

As we have seen, the likelihood that a low-income woman who is not eligible for Medicaid will be able to find a clinic able to supply implants at a price she can afford is largely a matter of chance. As you know, funding provided through Title X and other federal and state programs intended to increase access to family planning services for low-income women who are not eligible for Medicaid has decreased precipitously over the last decade. Consequently, funds are being allocated at the clinic level to provide services to the greatest number of women at the lowest possible cost; this strategy could lead to an overdependence on methods such as the pill, which do not require a long term investment, and which is usually available to clinics at a deep discount through manufacturers.

Other issues of access and quality of care play secondary but still important roles in making a new, unfamiliar method available to all women who wish to use it. Personnel policies, including who will be reimbursed for providing a contraceptive method, may often dictate which health care professionals will be authorized to insert or remove the device. In 13 states, physicians are the only personnel eligible for Medicaid reimbursement. In 30 states, nurse practitioners are also reimbursed; in 25 states and the District of Columbia, nurse-midwives; and in nine, physicians' assistants. Meanwhile, forty-nine percent of all clinics offering implants report that physicians alone perform implant insertions;

however, 64% of hospital providers stated that physicians alone can perform implant procedures. In contrast, 74% of Planned Parenthood affiliates reported using solely clinicians other than physicians to perform insertions.

The issue of removals, especially the lack of continuing education among providers, especially in removal techniques, may also prove to be an ongoing obstacle to providing adequate services. Few providers have much experience removing implants and may need refresher courses.

Moreover, the issue of early removals -- before the five year lifespan of an implant set has been reached -- will increasingly be faced by providers. Some women will be dissatisfied with the method, for some the circumstances of their lives requiring contraceptive use may change, and a few may have medical problems with the method. In each case, women must be assured that their provider is willing and able to remove the implants.

Up to this point, we have focused on the provision of Norplant through the public sector, largely to women who are eligible for Medicaid. However, it cannot be assumed that women who have private insurance coverage are in a significantly better position to obtain implants, unless they are able to afford paying for the device out-of-pocket. Data were recently released the recent AGI study of private insurance coverage of reproductive health services, conducted by AGI Policy Associates Rachel Gold and Daniel Daley, and Senior Research Associate Jennifer Frost, found that the historic tradition of covering surgical services and not preventive care remain strong. Since reproductive health care consists mostly of preventive care services, the implications are troubling, especially as the nation considers health care reform. Given traditional practices, sterilization -- the most common form of contraception in the U.S. today -- are routinely covered by at least 85% of all types of typical insurance policies. Coverage of abortion follows much the same pattern; two-thirds of all the policies included in our survey routinely cover abortion.

In sharp contrast, but in line with the traditional bias of health insurance against preventive care,

coverage of reversible contraception is uneven at best. None of the five reversible methods included in the survey – IUDs, diaphragms, Norplant, Depo Provera, and oral contraceptives – is routinely covered by any more than 40% of typical plans. Half of the large-group plans typically do not cover any method at all, and only 15 cover all five methods. It remarkable that oral contraceptives, the most commonly used reversible method, are only covered by one-third of the large-group plans. This is not the result of failure to cover prescription drugs; while 97% of large-group plans typically cover prescription drugs, two-thirds of the plans do not cover the pill.

Along these same lines, while over 90% of large-group plans cover medical devices in general, more than 80 percent of these plans do not cover IUDs or diaphragms, and three quarters do not cover Norplant. Only 24% of plans routinely cover all three components of Norplant: the device, insertion and removal. In addition, only 22% of large-group plans cover contraceptive counseling (critical to the satisfied use of Norplant).

The picture is significantly better for HMOs – only 7% provide no contraceptive coverage – but it should be noted that only 40% of the nation's HMOs cover all five contraceptive methods we studied. Furthermore, coverage for all three components of Norplant (device, insertion and removal) is less complete – only 46% – than for other reversible contraceptives. Still, contraceptive counseling is routinely covered by at least 90% of HMOs. Thus, about three fourths of the women who do have some form of private insurance coverage – not even taking into account women who are ineligible for Medicaid or other subsidy but also are not insured – are not covered should they choose Norplant as their contraceptive method.

Conclusion

Clearly, there is an ongoing demand from women and their partners, at all socioeconomic levels, for a wider range of choice of contraceptive methods. At a minimum, as a matter of national policy, we

should make all medically approved and effective contraceptive methods available to everyone who wishes to use them.

Clearly this is not the case now, and the problem is starkly demonstrated by the recent experience of the introduction of Norplant to the U.S. market. Our studies show that only poor women who are eligible for Medicaid, women who are not only covered by private insurance but who are fortunate enough to be enrolled in the minority of insurance plans that cover Norplant, and those women who are able to afford the upfront cost of an implant themselves, will be able to obtain it.

Given current funding and pricing policies, few other women will be likely to obtain and use Norplant. Title X family planning clinics, which were created to make all contraceptives available to anyone who wished to avail themselves of their services, currently cannot afford to provide fully subsidized implants to all of their clients. The fact that other methods are available at lower prices places clinics in the untenable position of subsidizing services for one woman who wishes to use Norplant, or many more women who may choose a relatively less expensive method (in its upfront cost) such as the pill. More than any other method, Norplant raises the issue of cost as the deciding factor in terms of which methods are made available or chosen rather than considerations of good health care or personal choice.

The Norplant situation is an extreme example, but cost factors may well affect the provision of other long-term, highly effective methods as well, such as IUDs and Depo Provera. Until comprehensive health care reform is enacted, we must try to fix the patchwork system of coverage under which we are now operating. Unless Norplant is made available at a public sector price that will allow clinics to offer it, and women to purchase it, or unless Title X funding is increased to a sufficiently high level that allows clinics to provide all methods to their clients free or at reasonable rates, few low- and moderate-income women will have real choice among methods. Yet the cold reality is that funding for Title X is unlikely to be increased even close to a level that would allow clinics to once again guarantee

access to all methods for all women who need them and cannot otherwise afford them.

This country has had long-standing public policy encouraging voluntary contraceptive use. Only when individuals are assured of making their own choices are they likely to be successful contraceptors. Consequently, all women and their partners must be provided the opportunity to easily obtain and to use contraception, along with complete freedom regarding which methods they choose. To accomplish this, family planning services should be included among basic preventive services provided under our health care system, without copayments, and all contraceptive methods must be covered.

Thank you for the opportunity to share these findings with you.

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